FEDERAL TRADE COMMISSION

I N D E X (PUBLIC RECORD)

WITNESS:	DIRECT	CROSS	REDIRECT	RECROSS
Kerr		6779	6821(US)	6947
			6954(US)	
			6955(SP)	
Safir	6961	6973	7037	

EXHIBITS	FOR ID	IN EVID
Commission		
Number 1668		6779
Number 1706		6779
Number 1731		6782
Number 1696		7033
Number 1697		7033
Schering		
Number 1277		7039
Upsher		
None		

OTHER EXHIBITS REFERENCED	PAGE
Commission	
CX 59	7013
CX 611	7013

1	CX 614	6978
2	CX 841	6784
3	CX 868	6816
4	CX 870	6808
5	CX 880	6814
6	CX 881	6819
7	CX 883	6812
8	CX 1546	7009
9	CX 1653	7019
10	CX 1695	7028
11	CX 1696	7032
12	CX 1714	6990
13	CX 1721	6996
14	Schering	
15	SPX 224	6889
16	SPX 225	6875
17	SPX 226	6881
18	SPX 237	6894
19	SPX 663	6975
20	SPX 1277	6963
21	Upsher	
22	USX 21	6834
23	USX 239	6827
24	USX 522	6864
25	USX 535	6868

USX 825	6893
USX 1026	6867
USX 1029	6866
USX 1601	6923
USX 1607	6825
USX 1609	6853
USX 1614	6805
USX 1622	6865

FEDERAL TRADE COMMISSION

In the Matter of:	)
SCHERING-PLOUGH CORPORATION,	)
a corporation,	)
and	)
UPSHER-SMITH LABORATORIES,	) File No. D09297
a corporation,	)
and	)
AMERICAN HOME PRODUCTS,	)
a corporation.	)
----------	)

Thursday, March 7, 2002

10:30 a.m.

TRIAL VOLUME 28

PART 1

PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL

Administrative Law Judge

Federal Trade Commission

600 Pennsylvania Avenue, N.W.

Washington, D.C.

Reported by: Susanne Bergling, RMR

For The Record, Inc.
Waldorf, Maryland
(301) 870-8025

APPEARANCES:

ON BEHALF OF THE FEDERAL TRADE COMMISSION:

KAREN G. BOKAT, Attorney
PHILIP M. EISENSTAT, Attorney
MELVIN H. ORLANS, Attorney
DAVID M. NARROW, Attorney
KARAN SINGH, Attorney
Federal Trade Commission
601 Pennsylvania Avenue, N.W.
Washington, D.C. 20580
(202) 326-2912

ON BEHALF OF SCHERING-PLOUGH CORPORATION:

JOHN W. NIELDS, Attorney
LAURA S. SHORES, Attorney
MARC G. SCHILDKRAUT, Attorney
CHARLES LOUGHLIN, Attorney
Howrey, Simon, Arnold & White
1299 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2402
(202) 783-0800

ON BEHALF OF UPSHER-SMITH LABORATORIES:

ROBERT D. PAUL, Attorney
J. MARK GIDLEY, Attorney
CHRISTOPHER M. CURRAN, Attorney
PETER CARNEY, Attorney
White & Case, LLP
601 Thirteenth Street, N.W.
Suite 600 South
Washington, D.C. 20005-3805
(202) 626-3610

ON BEHALF OF AMERICAN HOME PRODUCTS:

EMILY M. PASQUINELLI, Attorney
Arnold & Porter
555 Twelfth Street, N.W.
Washington, D.C. 20004-1206
(202) 942-5667

P R O C E E D I N G S

- - - - -

JUDGE CHAPPELL: Good morning, everyone.

ALL COUNSEL: Good morning, Your Honor.

JUDGE CHAPPELL: Any business before we resume your cross?

MR. EISENSTAT: A few housekeeping matters on the two documents yesterday that I had moved into evidence and that respondents' counsel had asked for time to review before we made a decision, and at this time I'd like to re-offer CX 1706 and CX 1668 into evidence.

JUDGE CHAPPELL: Any objection?

MR. NIELDS: No, I have had a chance to review them, and I have no objection.

JUDGE CHAPPELL: Thank you.

MR. GIDLEY: No objection, Your Honor, and we will seek in camera treatment. The reason is in the real world, the underlying world of the patent infringement case, my understanding is that these part of the proceedings in the Federal District Court were themselves under seal, Your Honor, and we have conferred with Mr. Eisenstat.

MR. EISENSTAT: And we have no objection to them moving to place these in camera.

JUDGE CHAPPELL: Okay, so --

MR. EISENSTAT: There is no need --

JUDGE CHAPPELL: -- am I hearing a motion for temporary in camera status until someone files a proper motion requesting in camera status, because it's going to take a motion.

MR. GIDLEY: Yes, Your Honor.

JUDGE CHAPPELL: I can grant it temporarily.

MR. GIDLEY: That's exactly what we're seeking, sort of a provisional ruling of this Court until we're able to put in a formal set of papers.

JUDGE CHAPPELL: Okay, and that would be for which document, both of these or one of them?

MR. EISENSTAT: That would be for both CX 1706 and 1668. Is that correct?

MR. GIDLEY: That's right. And the rationale, Your Honor, just so you have it on the record provisionally here and in a temporary fashion is that the proceedings inherently involve very sensitive intellectual property and patent formulation issues of Upsher-Smith, and we have conferred with Mr. Eisenstat.

JUDGE CHAPPELL: Okay, CX 1706 and CX 1668 are admitted into evidence, and I am granting them provisional or temporary in camera status pursuant to Rule 3.45(g) until a motion can be filed. Thank you.

MR. GIDLEY: Thank you very much. We will file that motion very shortly.

(Commission Exhibit Numbers 1668 and 1706 were admitted into evidence.)

JUDGE CHAPPELL: I'll remind you, sir, you are still under oath. You may proceed.

Was that all of the housekeeping matters that we had?

MR. EISENSTAT: Yes, Your Honor.

Whereupon--

WILLIAM O. KERR

a witness, called for examination, having previously been duly sworn, was examined and testified further as follows:

CROSS EXAMINATION (cont)

BY MR. EISENSTAT:

Q. Good morning, Dr. Kerr.

A. Good morning.

Q. Yesterday you mentioned that you had talked to some employees of Upsher-Smith about steps that would be necessary before Upsher-Smith could put their Klor Con M20 on the market. Is that right?

A. I did speak with some Upsher-Smith people about that, yes.

Q. Was one of them Vickie O'Neill?

A. Yes, I have spoken to Ms. O'Neill.

MR. EISENSTAT: At this time, Your Honor, I'm going to use another document which again I understand counsel for Upsher-Smith is going to request provisional in camera status until they have time to file the motion, and because we're going to be using it, I would request that Upsher-Smith, if they are going to ask for provisional status, do so now so that we can go in camera to review the document.

JUDGE CHAPPELL: Right, and just so you know, that the rule -- actually the new rule allowing provisional in camera status only applies to something offered into evidence.

MR. EISENSTAT: And I intend to offer this into evidence, Your Honor.

JUDGE CHAPPELL: And have you discussed with them whether they are going to object to admissibility?

MR. EISENSTAT: I have discussed that, and I understand Upsher-Smith has no objection to admissibility.

JUDGE CHAPPELL: Okay. Is this one document or more than one?

MR. EISENSTAT: It is just one document, Your Honor.

JUDGE CHAPPELL: Is there another one to follow

or --

MR. EISENSTAT: No, Your Honor, this will be the end.

JUDGE CHAPPELL: Okay, I just like to do these things in bunches.

MR. EISENSTAT: I understand.

JUDGE CHAPPELL: What document is this?

MR. EISENSTAT: This is a document labeled CX 1731.

MR. GIDLEY: And Your Honor, not to steal Mr. Eisenstat's thunder, first, we do appreciate his courtesy in bringing this document to our attention before court started to speeds things along. Second, Your Honor, as will become obvious without getting into the underlying details of the document, you will see that this bears directly on Upsher-Smith's proprietary patents.

JUDGE CHAPPELL: Okay, so --

MR. GIDLEY: So, we do not object to admissibility, and we do move provisionally for in camera treatment, and we will follow it up with a written motion to Your Honor.

JUDGE CHAPPELL: And then just to keep it neat and tidy, you will include all three of these documents in one motion?

MR. GIDLEY: That's correct, Your Honor.

JUDGE CHAPPELL: Okay, thank you.

Any objection, Mr. Nields?

MR. NIELDS: None, Your Honor. Well, I should say -- probably should say I need to look at it, as I haven't seen this before until just this moment.

JUDGE CHAPPELL: Okay.

MR. NIELDS: So, let me take a quick look at it before I consent to it coming into the record.

JUDGE CHAPPELL: Why don't you go ahead and look at it. We will just pause for a moment, unless you are going to need more than a moment.

MR. NIELDS: I don't think -- I think I should be able to do this quickly, Your Honor.

JUDGE CHAPPELL: Okay, thank you.

(Pause in the proceedings.)

MR. NIELDS: No objection, Your Honor.

JUDGE CHAPPELL: Thank you. What's that exhibit number?

MR. EISENSTAT: CX 1731.

JUDGE CHAPPELL: CX 1731 is admitted into evidence, and I am granting provisional in camera status to that document pursuant to 3.45(g).

(Commission Exhibit Number 1731 was admitted into evidence.)

MR. EISENSTAT: At this time, Your Honor, I would request that we go in camera so I can discuss the document with the witness.

JUDGE CHAPPELL: All right, Mr. Eisenstat.

I need the public to leave the courtroom, please. We are moving into in camera session. You will be notified when you are allowed to re-enter the courtroom.

(The in camera testimony continued in Volume 28, Part 2, Pages 7046 through 7048, then resumed as follows.)

BY MR. EISENSTAT:

Q. Dr. Kerr, in your discussion of the pro-competitive benefits of the Schering/Upsher-Smith settlement agreement, one thing you discussed was the ability of Upsher-Smith to get the Klor Con M10 on the market. Is that correct?

A. Yes, I did. That is a pro-competitive advantage of the settlement.

Q. The resolution of the patent case, that is, if it went to litigation and was resolved between Schering and Upsher-Smith, would that have resolved the issue of whether the coating on the Klor Con M10 product was covered and would have infringed by the '743 patent?

A. Not necessarily, no.

Q. Was the patent for the -- was the '743 patent, was that specific to a particular size pill?

A. I don't believe so, no.

Q. Do you know if Upsher-Smith used the same coating on the Klor Con M10 product as it did on the Klor Con M20 product?

A. I believe they did, yes.

Q. Back in 1997, do you know if Schering-Plough had a particular discount rate they used in their financial analysis when they were calculating net present value?

A. Yes, back in 1997, there were a number of records that told me what the discount rate was that they used internally.

Q. And did Upsher-Smith use -- excuse me, did Schering use a discount rate that approximated their cost of capital?

A. I don't know if it approximated their cost of capital.

Q. Do you know what Schering considered their cost of capital back in 1997?

A. No, I don't know.

Q. Yesterday we were talking about CX 841 when the day ended. Do you have that document in front of you?

A. Can you tell me what it is?

Q. Well, why don't I just give you a fresh copy, that way we make it easier for everybody.

A. Yes, sure.

MR. EISENSTAT: Your Honor, may I approach?

JUDGE CHAPPELL: Yes, you may.

BY MR. EISENSTAT:

Q. Here's a new copy of CX 841.

A. Thank you.

Q. Do you recall seeing this yesterday at the end of the day?

A. Yes, I do.

Q. The -- do you see the company on the list called Akzo Pharma International b.v?

A. Yes, I do.

Q. And does the list indicate that Niacor-SR was not of interest to that company?

A. Yes. Yes, as I understand it, this is a list of all the companies whether they expressed an interest or not, and a number of them, as I testified yesterday, expressed no interest --

Q. And the company --

A. -- as of that time.

Q. -- the company Astra AB, do you see that company on here?

A. Yes, I do.

Q. And does the list indicate that Niacor-SR was not of interest to that company?

A. Yes. Again, there are many companies on here that are not of interest -- that expressed apparently no interest in this product.

Q. And do you see the next company on the list, Bayer AG?

A. Yes, I do.

Q. And does the list indicate that Niacor-SR was not of interest to that company?

A. Yes. That's another one of the companies on this list that expressed no interest. There are approximately three pages of companies, many of which expressed no interest.

Q. And the next company is Beaufour Ipsen International. Do you see that company?

A. Yes, I do.

Q. And does the list indicate that Niacor-SR was not of interest to that company?

A. Yes, that's what it says.

Q. And the next company is Boehringer Ingelheim. Do you see that?

A. Yes, I do.

Q. And does the list indicate that Niacor-SR was not of interest to that company?

A. Yes, that's another of the ones that's on the list that appears to say that there is no interest as of that time.

Q. And the next company is Boehringer Mannheim. Do you see that one?

A. Yes.

Q. And does the list indicate that that company was -- Niacor-SR was not of interest to that company?

A. Yes, at least at that time, yes.

Q. And the next company is -- and I apologize if I'm mangling the pronunciation -- but its Byk Gulden, do you see that name?

A. Yes.

Q. B Y K. And the list indicates that Niacor-SR was not of interest to that company. Is that right?

A. Yes, apparently that's what Mr. Pettit from Moreton concluded at that time, yes.

Q. And the next company is Cilag-Janssen Pharmaceutika b.v. Do you see that one?

A. Yes.

Q. And the list also indicates that Niacor-SR was not of interest to that company. Is that right?

A. Yes, so Mr. Pettit is apparently saying to Upsher at that time, yes.

Q. And the next company is DuPont Pharmaceuticals,

Limited. Do you see that?

A. Yes.

Q. And the list indicates that Niacor-SR was not of interest to that company. Is that correct?

A. Similarly, it appears that Mr. Pettit is reporting that to Upsher at this time, reporting on all the companies on the list apparently.

Q. Could you turn to the second page of the document. Do you see the first company at the top of the second page, Grunenthal GmbH? Do you see that company?

A. Yes, I do.

Q. And does the list indicate that Niacor-SR was not of interest to that company?

A. That's -- that is what the list indicates. It's another one of the companies that apparently Mr. Pettit is informing Upsher might not have an interest as of that date.

Q. And the next company is Hoechst Marion Roussel AG. Do you see that?

A. Yes, I do.

Q. And does the list indicate that Niacor-SR was not of interest to that company?

A. That's, again, what the list says, yes.

Q. And the next company is Knoll AG, K N O L L.

Do you see that one?

A. Yes.

Q. And does the list indicate that Niacor-SR was not of interest to that company?

A. Yes, it -- and apparently it cites a fax of March -- must be February 3rd, '97.

Q. Can we skip down to the company Leo Pharmaceutical Products A/S? Do you see that one?

A. That's the one after Lacer and Laboratoires Lafon?

Q. That's correct. Do you see it?

A. Yes.

Q. Do you see Leo Pharmaceutical Products?

A. Yes, I do.

Q. And does the list indicate that Niacor-SR was not of interest to that company?

A. Yes. Of course, it refers to the fax. If we could see the fax, it would be better to say it -- better to determine what was really the status of this and the other companies as well, but certainly that's what Mr. Pettit is reporting to Upsher at the time.

Q. And the next company is Luitpold Pharma GmbH. Do you see that?

A. Yes.

Q. And does the list indicate that Niacor-SR was

not of interest to that company?

A. Again, it refers to a fax that was received February 4th, but it is advising that at that point Luitpold is not -- is expressing no interest.

Q. And the next company is Meda AB, M E D A, AB. Do you see that one?

A. Yes, yes.

Q. And does the list indicate that Niacor-SR was not of interest to that company?

A. Well, it does, but it also says, "Response awaited. Reminder fax February the 21st, '97." So, it's not clear to me what that means, although it does say, "Advised as not of interest as of 28 February 1997."

Q. And 28 February 1997 is after the date of the reminder fax, February 21st, 1997. Is that right?

A. Well, February 28th is certainly after February 21st, but I'm -- just looking at this, we can't say much about what this -- looking at this document can't tell us whether -- what the phrase "response awaited" means.

Q. Is it your view that they were still awaiting a response after the 28th of February 1997?

A. Oh, I -- I don't know. I'm just -- you're asking me to read a document, and I'm reading the

document, but the document says, "Response awaited." It also says, "Advised as not of interest." I don't know which of those two things is the appropriate one.

Q. And the next company is Medeva plc. Do you see that one?

A. Yes, I do.

Q. And does the document indicate that Medeva plc has no interest in Niacor-SR -- Niacor-SR is not of interest to Medeva plc?

A. Again, this is Mr. Pettit advising that this company is not -- has no interest. It says, "Not of interest," and then refers to a fax.

Q. The next company is Merckle GmbH. Do you see that one?

A. Yes, I do.

Q. And under the Status column for that, the document reads, "Woke up on 18th March. Apologetic for delay. Now under review and they will revert as soon as possible. NB: Part of the EuroAlliance with Lacer in Spain. Lacer may, therefore, be responsible for awakening them from their slumbers. Have now advised as not of interest - see copy letter."

Do you see that?

A. Yes, I do.

Q. Did I read that correctly?

A. That's what it says, and it does refer to Lacer, which is above, and describes that they are in an alliance with Lacer, and if you look at the Lacer interest, it shows that Lacer was still in the process of reviewing --

Q. Did I read that correctly?

A. Excuse me?

Q. Did I read that correctly?

A. I won't certify that you read it correctly. It sounded like it was correct, yes.

Q. And the next one -- the next company on the list is Mundipharma International Limited. Do you see that listing?

A. Yes. Yes, I do.

Q. And do you see under Status it reads, "Not of interest - see fax dated January 28, 1997"?

A. Yes, this is another of Mr. Pettit's list of -- advising -- the list includes advising Upsher-Smith that certain companies were not interested in Niacor.

Q. Do you see the next company on the list, Novo Nordisk A/S?

A. Yes, I do.

Q. And do you see under the Status column it reads, "Have finally responded as not of interest"?

A. Yes, that's clearly what it says. Another of

Mr. Pettit's notes.

Q. Let's turn to the next page of the document. Do you see the company on -- the third page of the document, and it bears the Bates number USL 13150.

Do you see the company listed here called Recordati SpA?

A. Yes, I do.

Q. And do you see under the Status column it says, "Response awaited. Reminder fax February 21st, 1997. Advised as not of interest March 4th, 1997"?

A. You appear to have read it correctly, yes.

Q. And the next company on the list is Rhone Poulenc Rorer SA. Is that correct?

A. Yes, it is.

Q. And do you see under the Status column it says, "Response awaited. Reminder fax January 31st, 1997. Have to assume as not of interest. Not of interest - see fax dated February 3rd, 1997"? Do you see that?

A. Well, I think that's not correct.

Q. Okay.

A. No, that's -- that language is on the page, but it doesn't appear to relate to Rhone Poulenc.

Q. You know, I think you might be right.

A. It relates to Hoffman LaRoche apparently. The first part of that answer seems to relate to Rhone

Poulenc.

Q. It does appear that that particular line is -- let's go -- you say that appears to relate to Hoffman LaRoche, is that right, that bottom line?

A. Well, let's see, the first part that you read about response awaited, reminder fax, have to assume is not of interest --

Q. That appears to be --

A. -- relates to Rhone Poulenc.

Q. -- Rhone Poulenc Rorer, right?

A. Yes, it does.

Q. And then Hoffman LaRoche, the status would be, "Not of interest - see fax dated February 3rd, 1997." Isn't that right?

A. That's the way I would read this document. It looks as if Mr. Pettit is referring again to these two companies and what he has perceived about their interest at the time of the writing.

Q. And the next company after Hoffman LaRoche is Sanofi-Winthrop Limited. Do you see that?

A. Yes, I do.

Q. And under the Status column it reads, "Not of interest - see fax dated February 3rd, 1997." Is that right?

A. Yes, again, it refers to a fax which is not

here.

Q. And the next column is Schering AG. Do you see that one?

A. Yes, I do.

Q. And do you see under the Status column, it says, "Not of interest - see fax dated February 4th, '97"?

A. Similarly, Mr. Pettit is advising Upsher that the interest of this company, based on a fax that isn't -- that isn't here --

Q. Did I read that --

A. -- but as of this time --

Q. -- did I read that Status column correctly?

A. I don't remember now. I see what it says.

Q. Does it read, "Not of interest - see fax dated February 4th, '97"?

A. No -- oh, yes, it does. I think I'm looking at the wrong one. That appears to be what it says.

Q. The next company listed is Schering-Plough Limited. Do you see that one?

A. Yes, I see that.

Q. And under the Status column, it says, "Verbally advised as not of interest, January 31st, 1997."

Is that right?

A. That's what it says, yes.

Q. And you understand that Schering-Plough Limited is a subsidiary of Schering-Plough, one of the respondents in this case?

A. I do understand that, yes, but -- yes.

Q. And the next company list is Schwarz Pharma, do you see that, Schwarz Pharma AG?

A. Yes.

Q. And under the Status column, it reads, "Not of interest - see fax of January 28th, '97." Is that correct?

A. Yes, it's another list -- another listing from Mr. Pettit.

Q. And if we skip down, do you see the company called --

A. Past Searle and Servier?

Q. Past Searle, Servier, SmithKline Beecham, all the way down to Solvay Pharma SA. Do you see that?

A. Yes.

Q. And Solvay Pharma SA, under the Status column it reads, "Not of interest - see fax dated January 28, '97." Is that right?

MR. GIDLEY: Your Honor, I am going to object to this line of questioning. Just so our paper transcript is clear, the best evidence of Mr. Pettit's report is CX 841. If counsel wants to read snippets of

the document, I have no objection. I simply want to protect my paper record for someone who does not have CX 841 in front of them. We are obviously reading quite selectively.

JUDGE CHAPPELL: And what is this document that you are using right now, Mr. Eisenstat?

MR. EISENSTAT: This is a list of all the companies that we understand as of this time Mr. Moreton and Pettit had contacted in Europe with regard to the Upsher-Smith Niacor-SR product.

JUDGE CHAPPELL: No, what's the exhibit number?

MR. EISENSTAT: I apologize, Your Honor. The exhibit number is 841.

JUDGE CHAPPELL: Is this document in evidence?

MR. EISENSTAT: Yes, it is, Your Honor.

JUDGE CHAPPELL: He has the right to read or go over any document that's in evidence. The objection is overruled.

BY MR. EISENSTAT:

Q. We had just talked about Solvay Pharma. Do you see the company down below that UCB SA?

A. Yes.

Q. And does the Status column there indicate, "Not of interest - see fax dated February 7th, '97"?

A. Yes, that's -- that seems to be what it says on

this list -- on this line.

Q. And under that, there's a company called Yamanouchi Pharmaceutical bv, and again, I apologize if I've mangled the pronunciation. Do you see that company?

A. Yeah, I think you probably did it much better than I could have.

Q. And under the Status column once again there it reads, "Not of interest - see fax dated February 4th, '97." Is that right?

A. Yes. Certainly it looks again like Mr. Pettit is informing Upsher that Yamanouchi is not interested. This is a list that includes a number of companies both of which -- some of which are interested, some of which are not.

Q. And the last company there on that page is Zeneca --

A. Excuse me, but --

Q. -- Group plc.

A. -- I wasn't able to finish --

Q. Sir, I asked a simple yes or no question and now I am going on to the next matter, Zeneca Group. Do you see that one?

A. I see a listing for Zeneca Group plc.

Q. And under the Status column, does it not read,

"Verbal advised as not of interest 2/4/97"?

A. That is indeed what it reads, another notation of Mr. Pettit's.

Q. Now, let's go back to the beginning of the list, let's go back to the first page, which bears the number USL 13148. Are you back on that page?

A. Yes, I am.

Q. Now, if we go down the list, there's a company we hadn't talked about before called Asta Medica AG. Do you see that one?

A. I see Asta Medica. I don't recall if we've spoken about that one before.

Q. Okay. Now, under the Status column, the status of that one reads, "Response awaited. Reminder fax 31.01.97. Have to assume as not of interest." Do you see that one?

A. I see that, yes.

Q. And if we go down that same page, we get to Ferring AB. Do you see that at the bottom of the page?

A. Yes, yes, it's on the bottom of the page, yes.

Q. And the status of Ferring AB under the Status column reads, "Response awaited. Reminder fax 31.01.97. Have to assume as not of interest." Is that how that reads?

A. That's what it says, yes.

Q. Turn to the next page, and go down to a company -- and this I won't even try to pronounce. It's spelled H A F S L U N D, and then the second word is N C Y O M E D, AS. Do you see that name?

A. Yes.

Q. And for that company, the status is reported as, "Response awaited. Reminder fax 31.01.97. Have to assume as not of interest." Is that correct?

A. Yes, that's what it says. It's interesting, that's one -- I think one of the companies that was on the exhibit that we used yesterday or the day before, but yes, that's what it says. That apparently is Mr. Pettit's assumption.

Q. And could you turn to the third page of the document, the document -- the page bearing the number USL 13150. Do you have that page in front of you?

A. I do, yes.

Q. And do you see the first company listed there, Prodesfarma SA?

A. Yes, I do.

Q. And under the Status column, does that Status column entry read, "Response awaited. Reminder fax 21.02.97. Have to assume as not of interest"?

A. Yes, yes. Again, referring to a fax, but it is -- that's what it says.

Q. And go down to SmithKline Beecham plc. Do you see that?

A. Yes.

Q. And under the Status column for SmithKline Beecham plc, does that Status column read, "Response awaited. Reminder fax 31.01.97. Have to assume as not of interest"?

A. Yes, yes, that's what it says. Again, that apparently is Mr. Pettit's report to Upsher-Smith about what that company was doing at that time or his assumption thereto.

Q. And do you see the company Zambon Group SpA, the second to the last entry on the page?

A. Yes, I do.

Q. And does the response -- in the response column there read, "Response awaited --" excuse me, in the Status column read, "Response awaited. Reminder fax 21.02.97. Have to assume as not of interest"?

A. Yes, that's what it says.

Q. Now, there's still companies on the list we haven't talked about, so I would like to stick with the list and go back to the first page, if you would.

A. Sure.

Q. The first company listed there is Abbott Laboratories. Do you see that?

A. Yes, I do.

Q. And the status there is, "Woke up on 19th March. Change of VP in licensing. Now under review. Process will take two to four weeks. Somewhat apologetic." Do you see that?

A. Yes, I do.

Q. Do you know whether Abbott Laboratories, Inc. ever expressed any interest in Niacor-SR as a licensing deal?

A. Well, I think the fact that this language, if it's correct, indicates that they did express some interest. They were -- the product was under review according to Mr. Pettit, and that's an indication of interest.

Q. And that meets your threshold as to what it means to be an indication of interest?

A. Well, it certainly is an indication of interest. If they weren't -- if they are reviewing it, they are at least interested in it. That doesn't mean that in the end they'll accept it, but it does mean they're interested in it.

Q. Do you know if after they finished their review they expressed any further interest in Niacor-SR?

A. No.

Q. Do you know what documents companies were sent

initially by Mr. Pettit to determine if there was an expression of interest in Niacor-SR?

A. Yes.

Q. And what documents were sent initially?

A. Well, that's a good point. I think initially, the information was very, very sketchy. It was a very brief mention of what the product was, what it would do, and offering a license opportunity. It was not -- there was not very much information at all. Subsequently, more information was sent out as companies got -- expressed some interest.

Q. And that was after the company had signed a confidentiality agreement?

A. Well, there was more -- I think there was more information in between there, but certainly after the companies agreed to a secrecy agreement with Upsher, additional information -- even more information was sent, yes.

Q. Do you see the list -- on the list on this page, again talking about CX 841, do you see on that list a company called Alpha Wassemann?

A. I do, yes.

Q. And under the status it says, "Initial contact made 21 April (EuroAlliance)." Do you see that?

A. Yes.

Q. Do you know what "EuroAlliance" means?

A. It's a group of pharmaceutical companies in Europe.

Q. It's a trade association?

A. Oh, no, no, I don't think it's a trade association. It's more of a joint venture and marketing organization. I don't know the corporate details of it.

Q. Do you know if Alpha Wassemann ever expressed any interest in Niacor-SR?

A. I don't know specifically about Alpha Wassemann, but again, EuroAlliance is, again, that entity that was referred to earlier I think in reference to Merckle, which we have already looked at, which then refers back to Lacer, which is a Spanish company, and EuroAlliance member Merckle referred it to Lacer.

My understanding is that in the EuroAlliance, the individual companies share things such as research and development and access to these --

Q. Let me make sure I understand. Do you have any understanding as to whether Alpha Wassemann ever expressed any interest in Niacor-SR?

A. I don't, but as I say, it refers to EuroAlliance, and my understanding of EuroAlliance is

that the companies within EuroAlliance share their information on some of the -- their drug portfolio and research portfolio, and therefore, Lacer would probably be the -- if there's -- if this document is correct, if Mr. Pettit's impression is correct, it sounds like Lacer would be a -- the lead entity within EuroAlliance.

Q. Dr. Esteve Laboratorios, do you see that one? Do you see that listing down here?

A. Yes, I do.

Q. And that's a company that you have on your demonstrative 1614, is that correct, at tab 27 of your notebook?

A. Yes.

Q. And the next company, Pierre Fabre, is also a company that you have on your demonstrative, USX 1614. Is that correct?

A. Yes.

Q. And Lacer SA, again, is a company that you have on your demonstrative. Is that correct?

A. Yes. I think it's pronounced Lacer, they're Spanish, and that's the one I just mentioned that's part of the EuroAlliance.

Q. Again, I apologize if I mispronounce these.

A. I just happen to know that one.

Q. And the next one on the list under Lacer is Laboratoires Lafon. Do you see that one?

A. Yes.

Q. And under the status report, again it says, "Initial contact made 21 April," and again it refers to the EuroAlliance. Do you see that?

A. Yes.

Q. Do you know whether Laboratoires Lafon as opposed to EuroAlliance ever made any expression of interest in Niacor-SR?

A. Again, it would be the same as -- would be the same answer as with Alpha Wassemann above. There was contact made apparently by Mr. Pettit on April 21st, which I think is the date of this -- of this memo, and he notes that they are a member of EuroAlliance, as is Lacer, and apparently Merckle as well.

Q. Do you know whether Laboratoires Lafon as an entity ever expressed any interest in Niacor-SR?

A. No, but again, they wouldn't have to if they were able to do that through EuroAlliance.

Q. Pfizer Limited is on this page. Do you see that one?

A. Yes, I do.

Q. And under the status report for Pfizer Limited, the Status column, it reads, "Interest confirmed 12th

March 1997 and secrecy agreement requested from Upsher Smith in USA, by fax in first instance. Secrecy agreement mailed to Pfizer 24th March. NB: Pfizer can be very slow. Have arranged initial meeting with them 17th April. Have also spoken by phone and secrecy agreement should be available for collection on 17th April. Suggested revisions to secrecy agreement faxed to USL on 21 April."

Did I read that correctly?

A. You appear to have.

Q. Now, Pfizer's a company that you also have on your demonstrative, USX 1614.

A. Yes, I believe it's on that list. I'd have to check.

Q. Do you know if information, additional information, was sent to Pfizer?

A. I don't recall sitting here.

Q. Do you recall if Pfizer ever expressed one way or another whether their interest continued after this?

A. After -- after this memo?

Q. After this memo.

A. I don't know offhand. Sitting here, I can't recall which documents I've seen relating to Pfizer.

MR. EISENSTAT: Your Honor, if I may approach?

JUDGE CHAPPELL: Yes, you may.

BY MR. EISENSTAT:

Q. Dr. Kerr, let me show you a document labeled CX 870. This is a telefax message to Vickie O'Neill at Upsher-Smith from Moreton Marketing Limited, and it's signed by David Pettit dated 19 May 1997.

Dr. Kerr, do you remember seeing this document before?

A. Yes, I believe so.

Q. And do you see the fourth paragraph down, the paragraph with one small sentence that reads, "Pfizer have advised that they do not wish to proceed"?

A. Yes. Let me read this. I see that that's what it says, yes. I think your question on Pfizer, though, was whether they expressed any -- whether they did anything after April 21st. This is May 19th, and it clearly says what it says, but there is that interim period, and we would have to look at that as well.

Q. But there's no doubt in your mind --

A. Dr. Esteve --

Q. -- there is no doubt in your mind that as of May 19th, 1997, Pfizer had advised that they do not wish to proceed?

A. No, that's what Mr. Pettit is reporting. I don't have any independent knowledge of that.

Q. Turn to the next page of the document, if you

will.

A. This is a single-page document?

Q. Excuse me, oh, go back to CX 841. I'm done with that document.

CX 841, do you have that in front of you again?

A. That's the Moreton list from April 21st?

Q. Yes. Do you have that list in front of you again?

A. Yes, I do.

Q. And if we turn to the third page of the document, the page with the Bates number USL 13150, do you have that?

A. Yes, I do.

Q. Do you see that? And under the Status, it says, "Direct contact established Upsher-Smith/Searle Chicago. Meeting arranged in Chicago for 28/29 May."

Do you see that?

A. Yes, I do.

Q. Now, Searle's a company that's also on your demonstrative, USX 1614.

A. I believe that's right, yes.

Q. And the next company, Servier, that's also a company that's on your demonstrative, USX 1614. Is that correct?

A. Yes. This is the one -- and that says it has

shown a very positive interest, secrecy agreement and so forth. There's a long list of --

Q. Sure.

A. -- information in that Status column.

Q. And if we go down the page, there's a company Synthelabo, do you see that, on Synthelabo?

A. Yes.

Q. And under Status it says, "Response awaited. Reminder fax 21.02.97. Not of interest at the moment but may have an interest in the future. Assume that they would like us to re-visit if we do not proceed with another company."

Did I read that correctly?

A. You appear to have read it correctly, yes.

Q. Do you know whether Synthelabo ever expressed any interest in Niacor-SR after the date of this memorandum from Moreton?

A. You know, I don't -- I don't remember the details of any particular company, no.

Q. Let's look at your demonstrative, USX 1614, which is tab 27 in your binder. Do you have that document?

A. I do, yes.

Q. And as I said before, Searle is on this list. Is that right?

A. Yes, it is.

Q. Do you have any understanding of whether Searle eventually rejected proceeding with Niacor-SR?

A. Let me see what I remember from the documents relating to Searle. In the end, the discussions with Searle, as I recall, went through a meeting in the United States, and then sometime after the agreement with Upsher-Smith and Schering-Plough was concluded, Searle was informed that another party had taken a license, and the discussions ended.

Q. You have no recollection of Searle telling Upsher-Smith that they were not interested in proceeding?

A. I don't think that that's -- no, I don't have any recollection of that, no.

Q. Did Searle ever make a monetary offer to license Niacor-SR?

A. Not to my knowledge, no.

Q. Let's look at Servier, which is also on your list. Do I have that right? Yeah, Les Laboratoires Servier. Is that right? That's on your list.

A. That seems right to me.

Q. And again, I apologize if I'm making these seem incomprehensible.

Now, Servier also actually had a meeting, did

they not, with Upsher-Smith?

A. Yes, apparently the date of the meeting was June 3rd, and that was one of the companies that Vickie O'Neill visited with Upsher-Smith staff and --

MR. EISENSTAT: If I may approach, Your Honor?

JUDGE CHAPPELL: Yes, you may.

THE WITNESS: -- in June of 1997.

BY MR. EISENSTAT:

Q. Let me show you what's been marked as CX 883. Have you finished reviewing the document, sir?

A. Just a second. (Document review.) Yes.

Q. Have you seen this document before?

A. Yes, I have.

Q. And this is a memo from Vickie O'Neill and Mark Halvorsen to Ian Troup and Ken Evenstad at Upsher-Smith Laboratories about the Servier presentation on June 3rd, 1997. Is that right?

A. Yes.

Q. Do you see -- under Meeting Comments, do you see the first paragraph where it reads, "Dr. Arnaud's general discussions during our presentation indicated that he had not thoroughly reviewed the documents previously sent or had looked at the potential market for Niacor-SR in Europe. Dr. Arnaud was not attentive during the clinical presentation and seemed distracted.

He expressed concern over the elevation in liver function tests (LFT) and whether the benefit of reduced flushing was a sufficient advantage over the increased risk of elevated LFTs."

Do you see that section?

A. I see that there's a paragraph there that says that, yes.

Q. Did Servier ever make a monetary offer for -- to license Niacor-SR?

A. No, not to my knowledge, although they continued discussions for some time.

Q. Another company on your list is Lacer SA, and that's a company you've mentioned a couple times. Is that right?

A. Yes, that's on the list. Again, I think it's Lacer.

Q. Lacer, and again, I apologize to you and the other people who know how to correctly pronounce these things, if --

JUDGE CHAPPELL: And to the stockholders?

MR. EISENSTAT: And -- yes, yes.

BY MR. EISENSTAT:

Q. And this is another company that Upsher actually went and met with in Europe. Is that correct?

A. Yes, I believe that meeting was in Spain at

approximately the same time as the Servier meeting, on the same trip.

MR. EISENSTAT: If I may approach the witness, Your Honor?

JUDGE CHAPPELL: Yes, you may.

BY MR. EISENSTAT:

Q. Dr. Kerr, let me hand you what's been marked as CX 880, and I'll give you a chance to look over the document.

A. (Document review.)

Q. Have you had an opportunity to review the document, Dr. Kerr?

A. Yes, I have.

Q. And again, this is a memo from Vickie O'Neill and Mark Halvorsen to Ian Troup and Ken Evenstad of Upsher-Smith Laboratories, Inc. regarding their meeting with Lacer SA. Is that correct?

A. Yes.

Q. Do you see on the first page of the document the section marked Next Steps? Do you see that section?

A. Yes, I do.

Q. And that paragraph reads, "Lacer will have an expert physician review the clinical data under a secrecy agreement. From this review, Lacer will make a

'go/no go' decision, as well as a determination of the number and type of patients that would be appropriate for Niacor-SR therapy."

Do you see that section?

A. I do, yes.

Q. Do you know if Schering-Plough ever had an expert physician review the clinical data for Niacor-SR before they entered into their agreement to license the product from Upsher-Smith?

A. I don't know that, no.

Q. Do you see the Summary section on this page?

A. Yes, I do.

Q. And the Summary section reads, "Lacer is a smaller player in the Spanish market but is actively promoting the establishment of lipid clinics and physician education. Overall, Lacer appeared moderately interested in Niacor-SR for the Spanish market."

Do you see that section?

A. Yes, yes, I do.

Q. Did Lacer ever make a monetary offer to Upsher-Smith for Niacor-SR, to your knowledge?

A. No, my understanding with respect to Lacer is that they continued going forward, I don't know if they finished their review, but by the time of -- by the

time of the June 17th settlement, they were still under consideration.

Q. Now, another company on your list -- and this is one I know I can't possibly pronounce -- it's Laboratorios Dr. Esteve SA. Do you see that?

A. I know it's on the list. I don't have that list in front of me.

Q. Okay. And that was another company that Upsher-Smith actually went and visited. Is that right?

A. Yes, it is.

MR. EISENSTAT: Your Honor, if I may approach the witness?

JUDGE CHAPPELL: Yes, you may.

BY MR. EISENSTAT:

Q. Dr. Kerr, let me hand you what's been marked as CX 868, and again, I'll give you a moment to go over the document.

A. Thank you very much. (Document review.)

Q. Have you finished reviewing the document?

A. Yes, yes, I have.

Q. And again, this is another memo from Vickie O'Neill and Mark Halvorsen to Ian Troup and Ken Evenstad of Upsher-Smith Laboratories regarding their meeting with Esteve SA. Is that right?

A. Yes, they met with Dr. Esteve in June of 1997,

and this is a report of the trip and a description of the meeting.

Q. And just so we're clear, when you say they met Dr. Esteve, that's the company and not the person they met?

A. Yes, yes. I don't know if they met with Dr. Esteve himself or herself. It is the company.

Q. Under the Next Steps, it says, "Dr. Miro will review the clinical information with the International group."

Do you see that?

A. Yes, I see that.

Q. And then step 2 is, "Forward data to the Clinical Medical Department if the International review is favorable."

Do you see that?

A. Yes.

Q. And the next step is, "Forward data to the Marketing Department in charge of pravastatin since they would have the most knowledge of the hyperlipidemia market."

Do you see that?

A. Yes.

Q. And then it says, "Esteve will get back to Upsher-Smith by the end of July with the results of

their review. Esteve would be interested in marketing in Spain and Portugal."

Do you see that?

A. Yes.

Q. Do you know if Dr. Esteve, the company, ever made a monetary offer to license Niacor-SR from Upsher-Smith?

A. No, they did not. As a matter of fact, they continued some discussions during the period of time, but by the time the decision was made, the settlement had already occurred, and it was moot.

Q. When you say "by the time the decision was made," what decision are you referring to?

A. Sometime later in that year, I believe that they corresponded, and Esteve decided that they didn't want the product, but that would have been back -- way back in -- it would be forward in September or October of '97.

Q. Oh, so it was September or October when they finally got back to Upsher-Smith?

A. Yes, I believe that's right. By that time, the settlement agreement had been in place, and the Kos product in the United States had changed the market for niacin products in a major way.

Q. And another company on your list is Pierre

Fabre?

A. Yes, I think.

Q. And that's another company that Upsher-Smith actually went and met with. Is that right?

A. Yes. As I recall, they met with them on the same trip, sometime in early June of 1997 in France.

MR. EISENSTAT: If I may approach the witness, Your Honor?

JUDGE CHAPPELL: Yes, you may.

BY MR. EISENSTAT:

Q. Dr. Kerr, let me hand you what's been marked as CX 881. Again, I'll give you a moment if you want to review the document.

A. (Document review.)

Q. Have you had a chance to review it, Doctor?

A. Yes. Yes, I have, thank you.

Q. And this is a memo, again, from Mark Halvorsen and Vickie O'Neill to Ian Troup and Ken Evenstad at Upsher-Smith Laboratories, and the subject of this memo is the Pierre Fabre presentation. Is that right?

A. Yes, it's a report of that meeting in early June, dated June 11th, 1997, just prior to the settlement agreement with Schering-Plough.

Q. And under Meeting Comments, the second paragraph, it reads, "The participants from Pierre

Fabre were very knowledgeable about the hyperlipidemia market, having licensed co-marketing rights to an HMG-CoA (fluvastatin) from Novartis in 1996. It was apparent they had reviewed our package on Niacor-SR and asked intelligent perceptive questions on the incidence of elevation in LFTs. Although they expressed concern over the high incidence at the 2000 mg dose, there was a good discussion on the appropriate use of niacin in combination with HMG-CoAs and the use of niacin at lower doses. Pierre Fabre appeared to understand that niacin could not be positioned in direct competition to HMG-CoAs or fibric acid compounds."

Do you see that section?

A. Yes, I see that paragraph, yes.

Q. Did Pierre Fabre ever make a monetary offer to license Niacor-SR from Upsher-Smith?

A. Well, there's some discussion of monetary matters on the next page. I don't know if that could be characterized as an offer or not. It certainly never became a final offer on either party, because ultimately the agreement with Schering-Plough and Upsher-Smith made it moot.

MR. EISENSTAT: If I may have a moment, Your Honor?

JUDGE CHAPPELL: Okay.

(Counsel conferring.)

MR. EISENSTAT: I have no further questions, Your Honor.

JUDGE CHAPPELL: Redirect?

MR. GIDLEY: Yes, Your Honor.

JUDGE CHAPPELL: Mr. Gidley, are you ready?

MR. GIDLEY: Yes, I am, Your Honor.

JUDGE CHAPPELL: Proceed.

MR. GIDLEY: May I approach, Your Honor?

JUDGE CHAPPELL: Yes, you may.

MR. GIDLEY: Thank you, Your Honor.

JUDGE CHAPPELL: Thanks.

REDIRECT EXAMINATION

BY MR. GIDLEY:

Q. Dr. Kerr, good morning. We are going to go through a couple of the topics Mr. Eisenstat addressed in the last day or so.

May I direct your attention to the binder that you've just been handed, and we will also make reference to the direct exhibit binder, so you may want to have that nearby.

A. Let me get that.

Q. Sir, I direct your attention to tab 1, which is a cull-out of some testimony heard at this hearing, sir, and if you would direct your attention to page

3606, this comes from the testimony of Dr. Horovitz, an expert retained I believe by the Schering-Plough Company.

Do you see page 3606, sir?

A. Yes, I do.

Q. And Dr. Horovitz quickly gives his background and says, "Yes, I have a Bachelor's in pharmacy and a Master's and Ph.D. in pharmacology, the science of how drugs work."

Do you see that quote, sir?

MR. EISENSTAT: Your Honor, I object. Dr. Horovitz's qualifications are well beyond the scope of my cross examination. I didn't go into his qualifications at all.

MR. GIDLEY: Your Honor, we are going to go directly to the subject matter of Niacor and Niaspan and the testimony in this courtroom on the safety, efficacy and comparability of those. The next question will link the two. I think, Your Honor, I would like to lay that foundation.

JUDGE CHAPPELL: Okay, how is it within the scope of his cross exam?

MR. GIDLEY: His cross exam centered chiefly for more than an hour on the comparison of Niacor and Niaspan. I intend to go right there.

MR. EISENSTAT: But I would object to his getting into the background of Dr. Horovitz. That -- my questions never touched on the background of Dr. Horovitz.

MR. GIDLEY: Your Honor, let me tell you -- I'll tell you exactly where I'm headed. Both during the voir dire and during some of the cross examination, the credentials of this witness compared to the questions that he was asked is an issue, and I want to address that, and that's my next question.

JUDGE CHAPPELL: I'll allow it. I'm overruling the objection, but don't make me regret this ruling, Mr. Gidley.

MR. GIDLEY: Thank you, Your Honor.

BY MR. GIDLEY:

Q. Dr. Kerr, do you have a Bachelor's in pharmacy?

A. No, I don't.

Q. Do you have a Master's in pharmacy?

A. No.

Q. Do you have a Ph.D. in pharmacology, the science of how drugs work?

A. No, I don't.

Q. Now, I call you "Dr." Your "Dr." is a degree in economics, sir?

A. Yes.

Q. Now, on the next page, there is a reference to the Licensing Executives Society. Do you see that?

A. Yes.

Q. Are you familiar with that society?

A. Yes.

Q. What is that society?

A. It's an organization of individuals who are responsible for managing the intellectual property of businesses, schools, other nonprofit organizations.

Q. May I direct your attention, sir, to Dr. Horovitz's testimony found at page 3626.

"QUESTION: Now, Dr. Horovitz, in addition to Niacor-SR, are you familiar with an additional product referred to as Niaspan?

"ANSWER: Yes.

"QUESTION: And do each of those products, Niacor-SR and Niaspan, have niacin as their active ingredient?

"ANSWER: Yes, those are both products that have niacin in a controlled release dosage form."

Do you see that, sir?

A. I do see that.

Q. And is that consistent with your understanding, sir, of Niacor and Niaspan?

A. Yes, absolutely.

Q. Sir, I'd like to direct your attention back to your direct exhibits binder, that's the Kerr binder, and could you go to tab 18, and tab 18 is USX 1607. Do you see that, sir?

A. Yes, yes, I do.

Q. And this is a plot from public data of the stock price -- excuse me, the market capitalization of the Kos Pharmaceuticals Company. Is that correct?

A. Yes.

Q. And that is an exhibit that you relied on in arriving at your professional opinion. Is that correct?

A. Yes, I did.

Q. All right. Now, sir, directing your attention to tab 2, the testimony of Mark Halvorsen, this is in the second book. Are you at page 3947 of the trial transcript in the hearing before Judge Chappell?

A. Yes.

Q. And sir, directing your attention to the yellow highlighted cull-out:

"QUESTION: And before it got approval, what type of information did you have about Kos' Niaspan product?"

Skipping down:

"ANSWER: I was looking for both safety and

efficacy information.

"QUESTION: And based on what you saw in June of 1997, how did Niaspan stack up to Niacor-SR?

"ANSWER: I felt they were virtually the same."

Do you see that?

A. I do see that.

Q. And how does that affect your opinion in this case, sir?

MR. EISENSTAT: Your Honor, if I may object again, in his expert report, Dr. Kerr never mentioned relying on anything in testimony by Dr. Horovitz or Mr. Halvorsen. We're just going way beyond the scope of his expert report and way beyond the area of my cross examination.

MR. GIDLEY: It was impossible for Dr. Kerr to rely on Horovitz and Halvorsen in that they had not testified at the hearing. Your Honor, I want to make sure that we have the foundation for the next series of questions, which go directly to the cross examination door opened, which I intend to go through, Your Honor, on the comparability of Niacor and Niaspan.

JUDGE CHAPPELL: Okay, I'm giving you some leeway here, Mr. Gidley, but I want to hear a question connecting this issue to his cross.

MR. GIDLEY: All right, Your Honor.

JUDGE CHAPPELL: Pretty soon.

MR. GIDLEY: Yes, Your Honor, very good.

JUDGE CHAPPELL: Overruled at this time.

BY MR. GIDLEY:

Q. May I direct your attention, Dr. Kerr, within this book to tab 11, USX 239. Do you see that, sir?

A. Yes.

Q. And is this one of the documents that Mr. Eisenstat showed you during his cross examination?

A. Yes, it is.

Q. All right, sir. And do you recall that you were asked about a series of additional drugs that Kos had in its product pipeline? Do you remember those questions?

A. Yes, they were drugs that were recorded in one of Kos' filings with the SEC.

Q. Now, directing your attention to page 854 of the exhibit that Mr. Eisenstat showed you, we've yellow highlighted three products from the Kos Company, and I show you what is a page dated May 12th, 1997 from the Dillon Read Company. Do you see that?

A. Yes. Yes, I do.

Q. Now, for product revenues for the Kos Pharmaceuticals Company, sir, in fiscal 1998, what were the estimated product revenues of Niaspan according to

Dillon Read?

A. That says $17.3 million.

Q. And what were the estimated revenues, sir, in that year for albuterol MDI?

A. Zero.

Q. And how about IS-5-MN?

A. Zero.

Q. And how about other?

A. Zero.

Q. So, in 1998, an investor looking at this would not be relying on albuterol, IS-5-MN or other for earnings or revenues for Kos if the investor chose to rely on this document, would they?

MR. EISENSTAT: Objection, Your Honor. It's a leading question.

MR. GIDLEY: I can rephrase it, Your Honor.

JUDGE CHAPPELL: It is leading, so I'll sustain it; however, you are withdrawing the question, correct?

MR. GIDLEY: Yes, I am, and I would be very pleased to restate it.

BY MR. GIDLEY:

Q. Would an investor that was looking at this document and counting on 1998 revenues be looking for revenues in 1998 from albuterol MDI?

A. No, certainly not at all.

Q. How about -- I'm sorry. How about IS-5-MN?
A. No.
Q. Directing your attention, sir, to the column that's marked 1999, do you see that?
A. Yes, I do.
Q. Now, an investor that chose to rely on this Dillon Read report would see what estimate for Niaspan's future revenues in that year?
A. $91.8 million.
Q. And how about for albuterol MDI?
A. 169 -- I'm sorry, zero, zero in '99, yes.
Q. All right. And how about for IS-5-MN?
A. Zero.
Q. And how about for other?
A. Zero.
Q. For all of Kos Pharmaceuticals, according to this brokerage firm, the revenue in 1999 would be attributable to what product?
A. All for Niaspan, yes.
Q. Sir, directing your attention to the year 2000 -- and I take it, sir, this -- how far ahead in the future would this be for an investor in May of 1997?
A. It would be at least three years.
Q. All right. And in this year, as of May 12th,

1997, what was the revenue that Dillon Read was projecting for Niaspan?

A. $169.3 million.

Q. And how about for albuterol MDI?

A. $2.4 million.

Q. And how about for IS-5-MN?

A. $5.2 million.

Q. And how about for other?

A. Zero.

Q. All right, sir.

May I approach, Your Honor?

JUDGE CHAPPELL: Yes, you may. We're going to take a break sometime just after 12:00, Mr. Gidley.

MR. GIDLEY: Very good, Your Honor.

BY MR. GIDLEY:

Q. Dr. Kerr, according to the Dillon Read Company, for the year 2000, of the products that future revenues were being projected, what percentage of the 2000 revenues were accounted for by Niaspan, sir? And I have handed you, for the record, a calculator.

A. It looks to be about 96 percent.

Q. All right, sir. And what numbers are you comparing?

A. The revenues that are shown for Niaspan, $169 million, compared with the total revenues for the

company, which are -- which show up here at $176.9 million.

Q. And how about for albuterol MDI, IS-5-MN and other combined, what would they be approximately in 2000 according to Dillon Read as of May 12th, 1997?

A. That would be approximately 4 percent.

Q. All right. How about the year 2001 -- first of all, what's the difference in time now between May 12, 1997 and 2001?

MR. EISENSTAT: Objection, Your Honor, lack of foundation. The document refers to I believe a fiscal 2001, and I don't think we know whether this witness knows what that year would encompass.

JUDGE CHAPPELL: Sustained.

BY MR. GIDLEY:

Q. Dr. Kerr, do you have any basis for a belief one way or the other as to whether this is a calendar year or a fiscal year ending at a different date?

A. It does indicate on the document that it's F2001, F2000, that generally implies a fiscal year.

Q. Directing your attention, sir, to the prior page, SP 13853, there's a footnote that appears, "Fiscal year ends June 30"?

A. That's right.

Q. Do you see that language?

A. Yes, I do.

Q. And sir, what would be your view of the meaning of that footnote?

A. That Kos was using a fiscal year rather than a calendar year, and the fiscal period that they use is one that ends June 30th. So, fiscal 2001 would end June 30th, 2001.

Q. And similarly, fiscal 2000 would be the year ended June 30, 2000, sir?

A. Yes.

Q. And fiscal 1999 would be the 12-month period ending June 30, 1999, sir?

A. Yes.

Q. And fiscal 1998 would be the 12-month period ended in 1998, June 30, 1998?

A. Yes.

Q. Is that your understanding?

A. Yes.

Q. Now, sir, directing your attention to fiscal 2001, I would ask you to compare the product revenues projected by the Dillon Read Company for Niaspan against the total revenues that that brokerage firm was projecting for fiscal 2001.

A. Well, they were projecting sales for Niaspan of $242.8 million in fiscal 2001, and the total revenues

were $2 -- were projected to be $258.7 million. So, if I can use the calculator for a minute, that comes to about 94 percent.

Q. Ninety-four percent of what, sir?

A. The Niaspan would be shown as 94 percent of the expected revenues of Kos.

Q. And how about albuterol, IS-5-MN and other combined, sir, what would they be approximately for the fiscal year ended June 30, 2001, according to the Dillon Read Company on May 12th, 1997?

A. That would be about 6 percent.

MR. GIDLEY: Your Honor, we are done with this exhibit. We can take our break if it would please the Court.

JUDGE CHAPPELL: Let's take our morning break at 11:59. We will recess until 12:15.

(A brief recess was taken.)

JUDGE CHAPPELL: Mr. Gidley, you may continue.

MR. GIDLEY: Thank you, Your Honor.

BY MR. GIDLEY:

Q. Dr. Kerr, yesterday Mr. Eisenstat asked you a question:

"QUESTION: In your work, you have referred to Kos as a single-product company. Is that right?

"ANSWER: Yes."

Do you recall that testimony?

A. Yes.

Q. And sir, now that we've taken a little bit more time with USX 239, the Dillon Read document dated May 12th, 1997, what is your view of whether or not this document supports or does not support your opinion in this case?

A. It's very clear that the document, not only the Dillon Read document, but the Cowen document and the other information that was in the record at the time fits the conclusion that Kos was essentially perceived as a one-product company. Its stock performed based on the expectations for Niaspan, and failed to perform when those expectations proved not to be as optimistic -- not to be as good as they had previously been expected to be at the end of 1997 and through 1998.

Q. Let me direct your attention, if I could, sir, to tab 12, which is USX 21, and that's in the new binder.

Sir, USX 21 is a clean copy of the Kos Pharmaceuticals prospectus. Do you see that?

A. Yes.

Q. Now, yesterday there was a great deal of testimony from an internet version of the prospectus,

and I'd like to ask you some questions in response to yesterday's examination using USX 21, sir.

Do you recall Mr. Eisenstat asking you about the underwriters to Kos Pharmaceuticals?

A. Yes.

Q. And sir, on the front page, the lead underwriters are listed in USX 21. Is that correct?

A. Yes.

Q. And who were the lead underwriters?

A. Cowen & Company, Dillon Read and Salomon Brothers.

Q. And if I may, sir, would you direct your attention to page 51 within the document.

A. Yes.

Q. That's a page that's Bates numbered 991-0256.

A. Yes.

Q. USX 21. Sir, do you see that there's a list of underwriters on that page?

A. Yes.

Q. That's a fairly lengthy list, sir?

A. Yes, it is.

Q. And what are some of the firms listed on that page as underwriters for Kos Pharmaceuticals?

A. All of the -- virtually all the big names on Wall Street were there, Credit Suisse, Alex Brown, Bear

Stearns, PaineWebber, Prudential Securities, Morgan Stanley, Lehman Brothers. There's a large number.

Q. And the column that says Number of Shares of Common Stock, what is that, sir?

A. That's a disclosure that's required of these companies to let them know how many shares they have of the initial IPO.

Q. And is that, indeed, what's disclosed on page 51?

A. Yes.

Q. And sir, going to the first page of USX 21, is the role of Cowen & Company, Dillon Read and Salomon Brothers as the lead underwriters disclosed on the cover of this document?

A. Yes.

Q. And would that be available to investors?

A. Yes, and any publication they made concerning this stock, from the most minor, would require the company to say that they were making a market or prior to the IPO that they were the underwriters or one of the underwriters for this stock.

Q. Is this sort of disclosure unusual and limited to the Kos Pharmaceuticals IPO?

A. Oh, no. No, it's required on any kind of an IPO, and furthermore, not even an IPO. Subsequent to

an IPO, when a company is publicly traded, it's required that the people who are making a market in that stock disclose it and on an ongoing basis.

Q. Let me direct your attention to page 3 of the prospectus for Kos Pharmaceuticals, sir. At the bottom of the page there's a yellow highlighted passage. I'd like to read it to you.

"Niacin is a water soluble vitamin long recognized by the National Institutes of Health and the American Heart Association as an effective pharmacological agent for the treatment of multiple lipid disorders, including elevated low-density lipoprotein ("LDL") cholesterol, total cholesterol and triglycerides and low high-density lipoprotein ("HDL") cholesterol."

Do you see that?

A. Yes.

Q. Now, is that language that Mr. Eisenstat asked you about yesterday?

A. No, he didn't.

Q. You guys skipped right over that language, did you?

A. I guess we did.

Q. And sir, the National Institutes of Health or the American Heart Association, do they have a

reputation in the medical community?

A. Yes, they do.

Q. Is it a poor reputation in your experience?

A. Oh, no, they are kind of standards organizations. And this is the kind of information that I examined in the record, not only relating to Kos but relating to the Upsher niacin product back when I did the analysis and the valuation of Niacor, and this was an important part of that.

Q. At the top of page 4 appears the following language from the Kos Pharmaceuticals prospectus:

"Treatment with Niaspan demonstrated a 14% to 19% reduction in LDL cholesterol, a 25% to 35% reduction in triglycerides, an increase of 22% to 29% in HDL cholesterol, and a reduction of 24% to 29% in Lp(a). Moreover, Niaspan's controlled-release formulation and dosing regimen reduced the liver toxicity and intolerable side effects generally associated with currently available formulations of niacin. There can be no assurance that the FDA will approve the Company's NDA for Niaspan on a timely basis, or at all."

Do you see that?

A. Yes, I do.

Q. Sir, do you have an understanding of whether or

not Niaspan had been approved by the FDA at the time of the initial public offering of Kos Pharmaceuticals?

A. No. No, it hadn't. It was not approved until the end of July, I believe, 1997. Sometime in the summer of '97 at any rate.

Q. Was it guaranteed in March of 1997 that the FDA would, in fact, approve Niaspan?

A. No, not at all, and that is an important consideration as well, because they had to disclose in their IPO that they didn't have approval and that they couldn't guarantee approval certainly. They didn't know whether the FDA process was going to at that time work its way to conclusion and that they would ever be able to introduce their Niaspan product.

Q. Sir, do you have an understanding, this first sentence that I read, treatment with Niaspan lowering LDL and reducing triglycerides, are those good or bad effects? Do you have a general understanding of that?

A. Well, a very general one. I think we've established I'm not a pharmacologist, but certainly these are positive factors that Kos is disclosing.

Q. All right. And then in the next sentence there, there appear to be some other factors that are being disclosed to investors, liver toxicity and intolerable side effects generally associated with

currently available formulations of niacin. Do you see that?

A. Oh, certainly, and those are equally important, not only from an FDA perspective and a clinical perspective but from a marketing perspective, because failure to disclose something like that, a side effect or potential side effect of the product that is the most important product in your company's portfolio would be very important information to provide to the public and would have dire consequences if you did not disclose that.

Q. And sir, this business about liver toxicity, would that be available to investors generally?

A. Well, certainly this IPO, the prospectus is available to the public, and anyone who read this would see that there are -- there can be "intolerable side effects."

Q. And that sentence would tell investors that liver toxicity had been associated with some formulations of niacin, would it not?

A. Yes.

Q. I direct your attention, sir, to page 6 of the Kos Pharmaceuticals IPO prospectus.

A. Yes.

Q. The first sentence says, "The Company is a

development stage company. It has --" let's make sure we're on the same page.

A. Yes, page 6.

Q. "The Company is a development stage company. It has generated no revenues from product sales, and it does not expect to generate significant revenue from product sales for at least the next nine months."

Do you see that?

A. Yes.

Q. Why would that appear in a prospectus? Why is that important to investors?

A. Well, again, it's a material fact about the ability of the company to generate revenues, and generating revenues generates earnings.

Q. Is it distinct from companies that have a proven track record with products that are already being sold?

A. Yes, again, referring back to the prior material we were discussing, there is no guarantee that a product is going to be on the market, even in nine months, and you need to describe that, the benefits and costs of going forward with that product and getting to the market.

Q. And what does the next sentence on page 6 mean, "As of December 31, 1996, the Company's accumulated

deficit was $64.8 million"?

Do you see that?

A. Yes.

Q. What's this a deficit of?

A. Cash, dollars.

Q. Meaning what, sir?

A. It means that they have spent a great deal of money and they have incurred a great deal of debt.

Q. And what about revenue?

A. And that they -- well, the deficit -- they are not earning any revenue, so they are not working down that deficit.

Q. Let me direct your attention to a later sentence that appears in this paragraph, "The Company's ability to achieve profitability will depend, among other things, on its successfully completing development of its products, obtaining regulatory approvals, establishing manufacturing, sales and marketing capabilities, achieving market acceptance for its products and maintaining sufficient funds to finance its activities. There can be no assurance that the Company will be able to achieve profitability or that profitability, if achieved, can be sustained."

Do you see that?

A. Yes.

Q. And sir, "the company" there, what company is being referred to here?

A. That's Kos.

Q. Kos Pharmaceuticals?

A. Yes.

Q. And sir, why would they be discussing a risk about manufacturing, sales and marketing capabilities in March of 1997?

A. Because at that time, their capacity in that area was quite rudimentary. They had not yet developed the sales and distribution force that they intended to use, nor had they gone far in the production of their products and manufacturing.

Q. In the spring of 1997, was it guaranteed that Kos would be able to achieve profitability?

MR. EISENSTAT: Objection, Your Honor, as leading.

JUDGE CHAPPELL: It doesn't suggest an answer. Overruled.

THE WITNESS: No, certainly not. I mean, that's essentially what they are disclosing in this case. They're disclosing that there are a great many hurdles that Kos will have to overcome in order to attain profitability. Not only do they have to make sure that they get their FDA approval for Niaspan, they

also have to set up their marketing and distribution system. They have to set up their manufacturing system and make sure it gets approved.

That's a time-consuming process, that's a difficult process, and there is absolutely no guarantee that it's going to happen, or if there -- also, there is no guarantee that if it happens, that if they get their manufacturing going and their marketing and distribution in place, that once they do it the costs will be such that they will be able to attain profitability.

BY MR. GIDLEY:

Q. Did you cover this language yesterday with Mr. Eisenstat?

A. No. No, we didn't do this.

Q. Let's go to the next section, Uncertainties Related to FDA Approval of Niaspan. I believe it's the fourth sentence that reads, and it's highlighted, "If the FDA believes that the results of the pivotal clinical trials for Niaspan do not establish the safety and efficacy of Niaspan in the treatment of any or all of the referenced indications, or if the FDA fails to accept that the long-term patient benefits from the treatment of such indications has been established, the Company will not receive the approvals necessary to

market Niaspan. Failure to obtain FDA approval to market Niaspan would have a material adverse effect on the Company."

Do you see that?

A. Yes, I do.

Q. Was FDA approval of Niaspan important to Kos Pharmaceutical investors in the first half of 1997?

A. I would say it's essential, yes, something that they would look to and expect if they are going to reward Kos in the marketplace.

Q. It says further, "The Company may be required to conduct additional clinical trials in order to demonstrate the safety and efficacy of Niaspan, which trials also may not be acceptable to the FDA."

Do you see that?

A. Yes.

Q. And would that be an adverse event for Kos Pharmaceuticals at this time?

A. Absolutely. That's why the disclosures are here, because of the significance of FDA approval for the Kos product line. It's absolutely essential that Kos at this time discloses that none of this is certain, that there are a number of regulatory as well as commercial hurdles that must be overcome prior to them being a profitable company.

Q. Do you recall in the last exhibit we were calculating revenues, you were doing this with IS-5-MN? Do you remember that?

A. Yes.

Q. All right. Mr. Eisenstat asked you about isosorbide-5-mononitrate.

A. Yes.

Q. Do you think that's the same thing as IS-5-MN?

A. So I understand, yes.

Q. All right. And now, let's direct your attention to the top of page 7 of the Kos Pharmaceuticals prospectus. The second sentence reads -- the second sentence reads, "Although the Company recently submitted an NDA to the FDA for Niaspan, each of its other products under development is at an earlier stage of development."

Do you see that?

A. Yes.

Q. Why would that be important to Kos Pharmaceutical investors in the spring of 1997?

A. Well, it's an indication that -- if you'll recall the discussion -- my discussion the other day about how the expectations of the pharmaceuticals companies about products that are early in development and late in development get better and better, the

probabilities get better and better as you get closer, it's important for the consumer -- for the investors to be told that many of the -- in fact, all of the other products are at earlier stages of development.

Only the Niaspan product is even close to the market. Assuming that the NDA is accepted and FDA approval is obtained, Niaspan is the product that they should rely on for the near future.

Q. Let me direct your attention to page 24, a section of the Kos Pharmaceuticals prospectus entitled Products Under Development. We have most of it up on the screen as well, Dr. Kerr.

A. Thank you.

Q. But why don't you work with the book, I think it's a bit easier to read.

A. Um-hum.

Q. Dr. Kerr, directing your attention to page 24, do you see the chart Products Under Development?

A. Yes.

Q. There's four columns there.

A. Yes.

Q. And sir, do you see the column that says Regulatory Filing?

A. Yes.

Q. Have you developed over the years some

familiarity with the approval process for pharmaceuticals as an economist?

A. Yes.

Q. Directing your attention to the phrase "NDA," what does that refer to?

A. That is a new drug application. It's an acronym that represents an FDA filing status.

Q. How about an ANDA, what is that, sir?

A. ANDA, the A in ANDA stands for abbreviated. It's an abbreviated new drug application.

Q. I would ask you to take a minute and read the development status of each of the products that are listed in this chart, including isosorbide-5-mononitrate, Niaspan and other products listed there.

A. Yes, the isosorbide 5, the product you were mentioning before, requires an ANDA, A-N-D-A. The other three products in the cardiovascular category are all NDA drugs, new drugs.

Q. And sir, asking you to refer to Development Status for all of these drugs -- so you may want to take a minute -- first, sir, on Niaspan, what was the regulatory status according to the Kos Pharmaceuticals IPO prospectus at this time period?

A. It's -- the NDA, the new drug application for Niaspan, had according to this been submitted in May of

1996.

Q. Do you recall Mr. Eisenstat asking you yesterday about albuterol CFC and albuterol non-CFC?

A. Yes.

Q. Are they contained in this chart?

A. Yes, they are. They are down in the respiratory area.

Q. Now, what sort of products are they?

A. They are respiratory products, beta agonists.

Q. And sir, for any of the products other than Niaspan at this time, had Kos Pharmaceuticals, according to its prospectus, submitted regulatory filings with the Food and Drug Administration?

A. There are none on this page, no.

Q. All right. How about -- let's just -- let's just hit this one more time. Isosorbide-5-mononitrate, what was its status?

A. Clinical pharmacology commenced in November of 1996, that's what it says here.

Q. How about albuterol CFC?

A. That had a clinical validation study completed with clinical pharmacology commenced in January of 1997.

Q. Had anything been filed with the FDA on albuterol CFC?

A. Apparently not.

Q. How about albuterol non-CFC, had there been an FDA filing?

A. Similarly, not, it's a formulation --

MR. EISENSTAT: Objection, Your Honor. We have had testimony in this trial that there are lots of kinds of FDA filings, and we haven't -- we don't know that this witness has any knowledge of other kinds of filings besides what's on here. So, how can he possibly testify whether there was some other kind of FDA filing with respect to these drugs at this time?

JUDGE CHAPPELL: Are you suggesting a lack of foundation?

MR. EISENSTAT: Lack of foundation, yes, Your Honor.

JUDGE CHAPPELL: Sustained.

MR. GIDLEY: I'm happy to build that foundation, Your Honor.

BY MR. GIDLEY:

Q. Sir, I want to direct your attention to page 24 and talk about what the market would have known from the face of the Kos Pharmaceuticals prospectus, and from the face of page 24, sir, is there indication that the ANDA had been filed for isosorbide-5-mononitrate?

A. No, to the contrary.

Q. And similarly, would investors reading the prospectus alone have an understanding that the albuterol ANDA filing had been made as of the time of the prospectus?

A. No. No, again, to the contrary. It would be -- the inference that would be drawn and the clear indication is that there was no filing of an ANDA for the one drug and an NDA for the other.

Q. And finally, from the standpoint of investors relying on the prospectus, from the face of the prospectus, does it appear that the NDA for albuterol non-CFC had been filed as of the time of the prospectus?

A. No, it does not.

Q. Directing your attention to the top of the page, it says in the third sentence, "For products currently under development, the Company typically will be required to perform Phase I clinical pharmacology and Phase III safety and efficacy pivotal trials; limited preclinical toxicology studies will also be required on some products."

Do you see that?

A. Yes.

Q. And is it your understanding that the FDA would require such testing?

MR. EISENSTAT: Objection, Your Honor, that's leading.

MR. GIDLEY: It doesn't suggest the answer, Your Honor. I'm asking for his understanding.

JUDGE CHAPPELL: I agree, I'm overruling the leading objection, but I would like to know a little more about how he has some understanding on that topic.

MR. GIDLEY: Fine, Your Honor.

JUDGE CHAPPELL: Thank you.

BY MR. GIDLEY:

Q. Sir, you work in the area of intellectual property. Is that correct?

A. Yes, yes, I do.

Q. And sir, have you served as a speaker in areas related to patents and intellectual property?

A. Yes.

Q. And prior to your work in this case, have you had occasion to work on intellectual property issues in the pharmaceuticals industry?

A. Yes, a number of times.

Q. All right. And over the course of your engagement, sir, have you developed any understanding of the FDA regulatory approval process?

A. Yes, and especially as they reflect on the work that I do, which is economic and financial analysis.

Q. All right. And have you had occasion to consider the FDA approval process in connection with the economic valuation of assets?

A. Yes.

Q. And sir, let me direct your attention back to the direct exhibit binder. Could you take a look, sir, at tab 23, at USX 1609? Do you see that?

A. Yes, I do.

Q. And it says, "Clinical Phase of Product, Phase I, Phase II, Phase III."

A. Yes.

Q. And what's the relationship between the clinical phase of the product and the third column in USX 1609?

A. The third column being the Average Dollar Amount? It -- the -- as the phase of development of the product goes up, as the clinical phase of the product goes up from phase I to phase II to phase III, the dollar value of the technology agreements that are reflected in this exhibit increases.

Q. And those phases, phase I, phase II, phase III, what do they refer to?

A. They refer -- they refer to phases of FDA approval, different kinds of tests that need to be -- that need to be made for drugs during the period as

they progress from the discovery stage to the market.

Q. May I direct your attention now to page 25, sir, of the prospectus for Kos Pharmaceuticals.

A. I'm sorry, Mr. Gidley, that was page 2 --

Q. Twenty-five, sir.

A. Thank you.

Q. Specifically, I'd like to direct your attention to the second yellow highlighted sentence which begins, "In 1995."

A. Yes.

Q. Would you read that, sir?

A. Yes, "In 1995, the market for cholesterol-reducing drugs exceeded $2 billion in the United States and $5 billion worldwide."

Q. All right. And what is that the market potential for, sir, according to the Kos Pharmaceuticals prospectus?

A. It's for -- well, it's for cholesterol-reducing drugs, but it's presented to indicate that the potential for their Niaspan product, which is a drug that is intended to be a cholesterol-reducing drug, had a great deal of potential.

Q. According to the Kos Pharmaceuticals prospectus, what is the relationship, if any, between the United States and the rest of the world in terms of

the potential market for cholesterol-reducing drugs in 1995?

A. Well, it indicates that --

MR. EISENSTAT: Objection, Your Honor, lack of foundation. I don't believe it has any reference to the potential market.

MR. GIDLEY: Your Honor, the document speaks for itself, and I'm simply asking this witness what the document says, a form of examination used extensively by Mr. Eisenstat.

JUDGE CHAPPELL: Well, you did ask him according to the prospectus, so to the extent it's in there and he can answer that, it's overruled.

THE WITNESS: As I mentioned, the prospectus is reviewing the market potential for Niaspan, and as one of the major factors in determining what that market potential is, it discusses the overall market for cholesterol-reducing drugs, both in the United States and overseas, and according to the figures presented by Kos, the market in the United States for those drugs is $2 billion, the market worldwide is $5 billion.

Therefore, the market outside the United States is $3 billion, and I think your question was the relationship between the U.S. and the rest of the world. In other words, the rest of the world appears

to be significantly larger than the United States in terms of cholesterol-reducing drugs.

BY MR. GIDLEY:

Q. Let me direct your attention to page 26. This is a section of the prospectus called Overview of Niacin.

A. Yes.

Q. Do you see that?

A. Um-hum.

Q. There's reference made in the second sentence that's highlighted, "In numerous independent studies performed during the past 30 years, niacin has proved effective in reducing total cholesterol, LDL cholesterol and triglycerides, as well as in increasing HDL cholesterol."

Do you see that?

A. Yes.

Q. Is that something that would have been known to anyone looking at the face of the Kos Pharmaceuticals prospectus?

A. Certainly from the prospectus, and it was fairly well known in the drug community and the -- and even in public media at that time.

Q. And over what time period had these studies been conducted on niacin, sir?

A. In the past 30 years according to the Kos document.

Q. And sir, in the next paragraph, there is discussion of the following:

"Although niacin has demonstrated favorable efficacy on most major lipid components, adverse side effects associated with currently available preparations of niacin have prevented it from becoming widely used to treat hyperlipidemia. Immediate-release preparations of niacin generally are administered three times daily and can cause multiple flushing episodes, characterized primarily by facial redness and tingling," and so on.

Do you see that?

A. Yes, I do.

Q. Would an investor who took the time to read the Kos prospectus know that niacin has some flushing effect?

A. Yes, and also that the Niaspan product that Kos is putting forward is -- has the promise, according to Kos, of reducing the side effects that niacin otherwise has, those side effects being very well known at the time.

Q. And -- all right. Let me direct your attention to page 28. I understand you're not a pharmacologist,

but is it -- do you have an understanding of whether the data that's presented in the box about Niaspan's lipid-altering profile, is that data favorable or unfavorable as a product characteristic?

MR. EISENSTAT: Objection, Your Honor, vague, and favorable or unfavorable with respect to what? And as we all agree, this man is not a pharmacologist.

MR. GIDLEY: May I respond, Your Honor?

JUDGE CHAPPELL: Yes.

MR. GIDLEY: This witness obviously studies products as an industrial organization economist. He has a general understanding of product characteristics and I think was examined for more than an hour yesterday on a variety of almost esoteric topics about this particular product, Niacor-SR.

JUDGE CHAPPELL: So, you are asking from the context or perspective of an investment specialist?

MR. GIDLEY: I would ask from the context of someone who's studying products and looking at the market effects of information on the stock market, which is part of Dr. Kerr's analysis and not objected to by counsel for the complainant.

JUDGE CHAPPELL: I'll allow it. Overruled.

BY MR. GIDLEY:

Q. Directing your attention to the box appearing

on page 28, Marketing Strategy for Niaspan, sir, do you have an understanding at this point in time as to what the size of the Kos sales force was in the United States at the time of the prospectus?

A. It was relatively small. They had a plan to build a very large force detailing Niaspan, but it -- but as of the time of this prospectus, which was prior to the IPO in March of 1997, they had a very small force. I don't know the exact number.

Q. Well, directing your attention to --

A. They had no products to sell, but they had very few people out in the market selling.

Q. Directing your attention I believe to the third sentence, "The Company's initial sales force is expected to consist of approximately 70 field representatives and managed care specialists," do you see that?

A. Yes.

Q. Sir, how would that field sales force compare to larger, more established companies like Schering-Plough at this time?

A. It would be trivial compared to those. It would be very, very small. That's a small sales staff in the pharmaceuticals industry.

Q. The top of page 29, there's a disclosure made

in the Kos Pharmaceuticals prospectus about flushing, and it's a highlighted sentence.

"Although most patients taking Niaspan will flush occasionally, the Company believes that the combination of Niaspan's formulation, its dosing regimen and proper dose titration should result in an incidence of flushing episodes that are tolerable for most patients."

Do you see that language?

MR. EISENSTAT: Objection, Your Honor, and under the doctrine of completeness, I request that counsel finish reading the rest of the paragraph to the witness before we ask questions on it.

MR. GIDLEY: Your Honor, I have been shut down on the doctrine of completeness at least once with this witness. There is an opportunity, Your Honor, I believe for recross.

JUDGE CHAPPELL: Just what I was going to say, Mr. Gidley. I'm just wondering how you figured that out.

You'll have your chance to go over this in detail on recross, Mr. Eisenstat. Overruled.

BY MR. GIDLEY:

Q. Sir, do you see that there's disclosure made about the product feature of Niaspan in relation to the

phenomenon of flushing?

A. Yes, I do, and it relates back as a commercial matter -- I mean, the reason this is here relates back to what we mentioned a few minutes ago, that it's well known that niacin -- that the niacin products in general have a problem with flushing, and it's an indication here that even Niaspan will have some flushing, but the intent is to illustrate that Niaspan will be better than what was there before for niacin products.

Q. Let me direct your attention to page 33, sir, Patents and Proprietary Rights. Now, the disclosure is made here, sir, of certain aspects of patents and proprietary rights, including the following quote:

"The Company actively seeks, when appropriate and available, protection for its products and proprietary information by means of United States and foreign patents, trademarks, trade secrets and contractual arrangements."

Then skipping down, "Broad patent protection for new formulations or new methods of use in existing chemical entities is sometimes difficult to obtain and often of limited usefulness, primarily because the active ingredient and many of the formulation techniques have been known for some time.

Consequently, some patents claiming new formulations or new methods of use for old drugs may not provide meaningful protection against competition."

Do you see that?

A. Yes, yes.

Q. And sir, what is the message that Kos Pharmaceuticals was sending investors that would be reading the prospectus?

MR. EISENSTAT: Objection, Your Honor, to what the message that Kos Pharmaceuticals was sending. That's beyond the scope of the competence of the witness, I believe.

JUDGE CHAPPELL: Sustained.

BY MR. GIDLEY:

Q. Sir, did Kos Pharmaceuticals in its prospectus disclose that patents might not be ironclad?

A. That's a way of saying it, and that's clearly what they're doing in this case. They're putting the investors on notice that although they intend to apply or have applied for in some cases patents for their various products, having a patent does not provide them with what's been referred to elsewhere as monopoly power or market power, and primarily -- and for a product like Niacor, that's very important, because as we've mentioned, niacin is a well-known drug.

It has very -- there were a large number of niacin products already in existence at the time of this prospectus, some of them prescription, some of them not, and those provide competition to any new niacin product coming onto the marketplace. The same thing would be true in the potassium chloride products.

Q. Let me direct your attention to page 35, and at the top of page 35, directing your attention to the sentence that reads as follows:

"The Company has not yet established a sales and marketing organization nor has it yet marketed, distributed or sold any product."

Do you see that?

A. Yes, I do.

Q. What's being disclosed there to reasonable investors reviewing the prospectus?

A. Well, that's essentially a warning that even if the drug gets approved, they still have to build that marketing and distribution system in order to commercialize the product once it's produced and approved by the FDA.

Q. Let's set aside that exhibit for now, sir.

May I approach, Your Honor?

JUDGE CHAPPELL: Yes, you may.

BY MR. GIDLEY:

Q. Sir, I show you what's been marked as USX 522, and I would ask you to refer to tab 18 of your direct examination binder.

Sir, you testified a few minutes ago about the FDA approval coming subsequent to the Kos Pharmaceuticals IPO prospectus. Do you recall that?

A. Yes.

Q. And showing you USX 522, what would investors have learned about the FDA marketing clearance for Niaspan?

A. It would have been on or around July 29th. That's the date of this press release from Kos.

Q. Directing your attention back to USX 1607?

A. Yes.

Q. All right. When did Kos Pharmaceuticals become public?

A. In March of 1997.

Q. And what was the market capitalization in June of 1997 for Kos Pharmaceuticals per USX 1607?

A. By June of '97, the market cap had risen from $300 million to $400 million.

Q. And sir, after USX 522 and the FDA approval on July 29, 1997, what happened subsequently to the price of the Kos stock?

A. The price of the Kos stock continued up and, in

fact, it jumped right around the time of this. It's clear that the market was waiting for FDA approval and rewarded Kos when the approval was granted.

Q. Sir, let me direct your attention, if I could, to tab 6 of your redirect binder, USX 1622, and sir, would you identify for the record USX 1622?

A. Yes, that's a document that I prepared showing the daily stock price of Kos Pharmaceuticals from February through December of 1997.

Q. And generally, sir, what happened to the price of Kos stock approximately contemporaneous with the release of the news that Niaspan had been approved by the FDA?

A. It jumped significantly. It went up by approximately $5 over a short period of time.

Q. And that's from what level to -- when you say $5, what's that from a base of?

A. It was trading at around $35 a share for a period in mid-July, and then as the end of July occurred and the price -- and the FDA announcement appeared, the stock jumped and went up to just in the range of $38-$40 a share, something like that. It moved from the mid -- from the low thirties to the mid thirties to the upper thirties in a relatively short period of time.

Q. Sir, directing your attention to the right-hand portion of the slide and the period between October 27th and December 16, 1997, what happened to the price of Kos' stock?

A. It fell significantly. It was trading in the -- again, in the mid-thirties, even as high as the mid-forties, in October prior to the end of October, and then it fell dramatically.

Q. And sir, what news became public in that time period?

A. The primary news was that Kos had introduced its product, its Niaspan product, and sales were disappointing, that the market hadn't accepted the -- the pharmaceuticals market hadn't accepted Niaspan with the same optimistic fervor that Kos had been proposing in its prior market material.

Q. And sir, turning your attention to tab 7, USX 1029, do you see that?

A. Yes, I do.

Q. And sir, what is -- what did the market learn through The New York Times on November 13, 1997?

A. Well, the shares of Kos Pharmaceuticals fell 46 percent on the -- it goes on to say that it's on the 12th of November, 1997, and that -- it attributes that decline to the company releasing its first quarter

results showing sales of the new drug, Niaspan, were not rising as fast as analysts had expected.

Q. And sir, is there any mention here of albuterol products in this press release?

A. No.

Q. How about isosorbide-5-mononitrate?

A. No.

Q. Directing your attention to tab 8, that's USX 1026, what was the price -- the closing price of Kos Pharmaceuticals' stock on June 17, 1997?

A. $29.50.

Q. And directing your attention to tab 9, the closing price of Kos Pharmaceuticals' stock on November 11th, according to USX 1027?

A. $30.94.

Q. And where was Kos listed as a public stock, what exchange?

A. It was on the New York Stock Exchange.

Q. All right. Now, turning to the next tab, which is the very next day, November 12, 1997, what was the closing price for Kos' stock?

A. $16.56.

Q. And approximately how big is that stock dive between those two dates?

A. It's almost half. It's fallen to almost half

of its prior value on the second day.

Q. You can set aside USX 522.

Let me direct your attention, sir, if I could to tab 13 of that binder, USX 535. Can you identify USX 535?

A. Yes, I can.

Q. What is it, sir?

A. It is an investment analysis done by Dillon Read & Company dated April 21st of 1997, and it is a report on Kos Pharmaceuticals and a buy recommendation, in fact, of Kos Pharmaceuticals.

Q. You were asked yesterday in cross examination about whether firms underlying a public stock offering ever put the best face possible on their recommendations. Do you recall that question?

A. Yes.

Q. And sir, as you sit here today, have you seen any evidence that there was a securities manipulation or fraud involved in the Kos Pharmaceuticals stock?

A. No, of course not.

Q. How long have you been involved in various stages of the FTC investigation and trial of this case?

A. Two years or almost two years.

Q. I think you told Mr. Eisenstat yesterday spring or summer of 2000. Is that about right?

A. Yes, that's right.

Q. All right. And since that time, have you reviewed documents?

A. Yes, a large number of documents.

Q. Was it a significant quantity of documents? Can you give us some feel for the amount of material you've been through?

A. Thousands of pages.

Q. All right. And how about depositions, have you ever reviewed any depositions?

A. Yes, I have.

Q. All right. And in connection with your review of depositions and documents in this case, have you seen any serious suggestion that there was a securities manipulation involved in Kos Pharmaceuticals' stock?

A. No.

Q. Do you have a general awareness of whether securities fraud is legal or illegal in the United States?

A. It is illegal.

Q. Are there serious consequences if you choose to violate that law, sir?

A. Absolutely, yes.

Q. All right. That prospectus we saw earlier, is that document a legally regulated document? Do you

have an understanding about that?

A. Yes, I think I mentioned that the underwriters or the -- after an IPO, even after the IPO, the investment companies that make a market in the particular drug have to -- are required to provide notice if they are commenting on that stock.

Q. Are you aware of any SEC enforcement actions against the management of Kos Pharmaceuticals, including Mr. Bell, its leader?

A. No, I'm not.

Q. How about the underwriters, Dillon Read and some of the other firms, are you aware of any SEC investigation of those firms?

A. No.

Q. Are you aware of any SEC enforcement actions against either Mr. Bell, the other managers of Kos Pharmaceuticals or the lead underwriters?

A. No.

Q. Let me direct your attention to the body of the Dillon Read document. Is this a document you reviewed in connection with forming your opinion in this case?

A. Yes, I did.

Q. All right. And do you see under Niaspan, they have a section, A Drug Delivery Home-Run, on the first page of USX 535?

A. Yes, yes.

Q. Again, underneath that, there's reference to some NIH trials between 1975 and 1990. Is that correct?

A. Yes.

Q. And do you have an understanding generally whether the bullet points there are favorable for patients or unfavorable for patients?

A. Decreases in heart attacks, decreases in mortality, they all look to be pretty favorable.

Q. All right. And similarly, there's discussion here of niacin and side effects in the follow-on paragraph. Is that correct?

A. Yes, yes.

Q. What are some of the side effects that Dillon Read discussed in its April 21, 1997 document to investors?

A. The two that they mention in particular are flushing and "worse" liver toxicity.

Q. All right.

A. But they go on to talk about altering the pharmacokinetic profile of niacin and point out that Niaspan they expect would be better on those events than others.

Q. All right. And directing your attention to the

page that's Bates labeled USL 11514, "In 1996, the market for cholesterol-reducing drugs exceeded $2.8 billion in the United States and approached $6.0 billion worldwide."

Do you see that?

A. Yes.

Q. And sir, how would that affect or influence your opinion in this case?

A. Well, it did. It's one of the factors that I examined when -- examined when determining a value for the Niacor product. It was another estimate in the public in early 1997 of the size of the anticholesterol market in both the United States and overseas that was providing potential for both Niacor and Niaspan.

Q. Let me direct your attention to the next page of the Dillon Read document dated April 21, 1997. There's mention of sales of $250 million by F2001. Do you see that?

A. Yes.

Q. What was the Dillon Read estimate at this time according to this exhibit, sir?

A. Well, the -- as the title indicates and then later the body describes, the -- they were projecting Niaspan sales approaching $250 million in the U.S. alone in 2001, which is -- which they believe to be the

third full year of sales.

Q. And sir, directing your attention several sentences below, it says, "We have only assumed slightly more than a 6 percent market share by F2001, which we believe is very modest, especially in light of the early success of Lipitor. Furthermore, as Niaspan becomes more familiar to physicians, the real power of Niaspan, the fact that it is the only drug that moves all lipids in the proper direction, will allow some spillover in the segment of 4 million patients with elevated LDL cholesterol currently dominated by the statins. We have not included any patients in this category. Finally, we expect clinicians will recognize benefits of Lp(a), which Niaspan lowers by 24 percent."

Do you see that?

A. Yes.

Q. What was the significance of that to investors?

A. It's -- Dillon Read believes that Niaspan will do well in the cholesterol-reducing market. They -- as you mention, they have a -- they were projecting a 6 percent market share by fiscal 2001. And importantly, they're describing here explicitly competition between Niaspan and some statins, including one of the largest and best selling statins, Lipitor. They're indicating that Niaspan will do -- will hold its own and do quite

well against those.

Q. Let me direct your attention to the bottom of that section on sales. It says, "Our model completely ignores all international sales, which we expect Kos will out-license to a major drug company. Given the high incidence of CHD and hyperlipidemia in several major European countries, we would not be surprised if Niaspan achieved a few hundred million in sales overseas, with Kos collecting at least 30% of the revenues. Again, this is all upside."

How did that affect your opinion in this case, sir?

A. Well, it did. It indicated -- it indicated several things that were useful. One is it indicated that Kos itself was not going to go to Europe or outside the United States or at least Dillon Read believed that to be true.

Secondly, it indicated that there was a quite positive expectation that there would be a market for this product in Europe.

Q. Let me direct your attention to the page Bates numbered 517. It's the very next page. Sir, do you see the sales projection according to the Dillon Read Company?

A. Yes, I do.

Q. All right. And without getting the calculator out, what is the relationship between the expected Niaspan revenues and albuterol MDI and IS-5-MN and so forth?

A. The sales of the other products, even at the end of the period in 2000-2001, are expected to be trivial compared to the sales of Niaspan. Niaspan, even at -- let's see, in fiscal 2001, they're projecting $242.8 million for Niaspan, and $258.7 would be the total sales for the company that they are projecting.

Q. Let me direct your attention now to the Cowen document that is found at tab 14, SPX 225.

A. I have it.

Q. Is this one of the documents you reviewed in forming your opinion in this case?

A. Yes.

Q. Directing your attention within the document, the first paragraph reads, "Market Could Total $11B in 2000. The cholesterol market has terrific growth prospects, driven by a large patient population and the availability of effective and safe products. An estimated 30MM-plus people have elevated cholesterol, but only 26% are treated. We look for many cholesterol-lowering products to be successful because

of the robust market dynamics. Market sales should surge from an estimated $7 billion in 1997 to $11 billion in 2000."

Do you see that?

A. I do see that.

Q. And sir, how did this Cowen May 2, 1997 document enter in or affect your economic valuation in this case?

A. The paragraph that you just read and others are very clear indications that Cowen was quite optimistic about the sales of Niaspan and Niacor and was presenting investors with a picture that they thought the product would be good, the product would be successful, very successful, would be able to compete in the market for anticholesterol drugs, and that therefore, Kos would do well, and I think they rated it a strong buy.

Q. Directing your attention to the highlighted sentence in the middle of the next paragraph, "We forecast Niaspan sales of $20 million in 1997 and $250 million in 2000."

Do you see that?

A. Yes.

Q. And sir, what would be the significance of that to investors?

A. Oh, once again, it shows that the market is expected to be substantial for their Niaspan product, and that would generate significant revenues for the company. It would generate significant profits and earnings.

Q. Directing your attention to the bottom of the page where the quote appears, "Niacin is a drug of choice for cholesterol regulation according to the American Heart Association (AHA) and the National Institutes of Health (NIH). This is due to the fact that niacin produces an excellent blood lipid profile. It is the only agent that drives all lipid components in the appropriate direction."

Do you see that?

A. Yes.

Q. And again, is that a general benefit of niacin according to this document?

A. Yes, it's a general benefit -- it is a general benefit of niacin, and Niaspan is better than the general niacin products that were available at the time according to the information that's presented here.

Q. All right. Now, some different numbers appear on -- compared to some of the numbers we've seen on the next page, which is page 2 of this document, and it's --

A. Yes, I see it.

Q. Are you there?

A. Yeah.

Q. It's a chart entitled Kos Pharmaceuticals P&L Dynamics ($MM).

Do you see that?

A. Yes, I do.

Q. For the years 1994, '95 and '96, what were the sales of Niaspan?

A. Zero.

Q. How about for the period 1997E?

A. They are listed as $20 million.

Q. And the E refers to what?

A. Estimated. I also think that this is -- these are calendar years. A little bit -- a little while earlier we were talking about fiscal years. It looks as if Cowen is reporting these in calendar years.

Q. All right, sir. And in year 1997, was Cowen projecting sales for any of the other products that Kos had?

A. No, it wasn't.

Q. All of the sales were attributed to what product?

A. Niaspan, and the comments mention that they are assuming that Niaspan would be launched at the second

half of 1997.

Q. All right. And how about the comment that appears on the Total Revenue line that begins with the word "Dominated," how does Cowen characterize the total revenues of Kos Pharmaceuticals in the period between 1997 and 2000?

A. It describes them as being dominated by Niaspan through 2000, and once again, if we look back at the numbers, we'll see by far the largest share of sales, $250 million in 2000 out of $280 million, are Niaspan.

Q. Now, about what percentage in the year 2000 of the sales were being estimated to come from Niaspan?

A. 25/28ths, a very large percentage.

Q. Right. And how about for 1999?

A. Similarly, a very large percentage, $175 million out of $195 million.

Q. And how about for 1998?

A. $90 million of Niaspan out of $95 million total.

Q. That would be more than 90 percent?

A. Yes, it certainly would.

Q. At the bottom of the page, the next page, page 4 of the Cowen presentation, it says, "Kos should be profitable in 1998."

Do you see that?

A. Yes.

Q. All right. And that was the view of the Cowen firm as of May 2nd, 1997?

A. Yes.

Q. And how did that affect your opinion in this case?

A. Well, it affected my -- my opinion in this case because in general, this is what the market is hearing in early 1997 about Kos, about -- and in particular about Kos' Niaspan product. It's being told that it is going to be a successful product that will -- that people believe it. This is what's being picked up in the trade press, it's being picked up in the investment press. This is just a manifestation of it -- of that kind of optimistic information.

Q. Directing your attention to the top of page 7 of the Cowen presentation, Documented Clinical Benefits of Niacin Therapy, do you see that?

A. Yes, I do.

Q. All right, the first bullet describes research from what institution?

A. The NIH, which is the National Institutes of Health, the Coronary Drug Project presumably at NIH.

Q. And that was a study of niacin, was it?

A. Yes, niacin therapy.

Q. And how about the next two studies, what were they?

A. One study called the Cholesterol-Lowering Arthrosclerosis Study, and the third one is the Familial Arthrosclerosis Treatment Study -- excuse my slurring there, Arthrosclerosis.

Q. And the last one was from what institution?

A. Again, that's an NIH study, National Institutes of Health.

Q. Was that of niacin?

A. Yes.

Q. Let me direct your attention now to tab 15, sir, if I could. That's SPX 226.

A. Yes, it is.

Q. I direct your attention, if I could, sir, to page 2 of this document.

A. Yes.

Q. This is a document, by the way, from what institution?

A. It is from Salomon Brothers.

Q. And did Salomon Brothers act as an underwriter for Kos Pharmaceuticals?

A. It -- it did, and it -- it's not -- in addition to being from Salomon Brothers, it's the United States Equity Research portion of Salomon Brothers and in

particular the pharmaceuticals group.

Q. All right. So, is this from -- it's an analyst group?

A. Yes.

Q. I see. And again, directing your attention now to SPX 226, page 2?

A. Yes.

Q. Do you see the second yellow highlighted passage, "We believe that this potential for a compound annual return of $55% over the next three years -- although risky -- is attractive."

Do you see that?

A. Yes, I do.

Q. And it says, "The shares have performed well already, advancing by 50% from the IPO price of $15 in early March."

Do you see that?

A. Yes, I do.

Q. And the date of this document is what, sir?

A. This document was in -- it was in the spring, and it's actually May 9th, May 9th of 1997.

Q. Now, if you had bought shares at the IPO, how would you characterize the return in this two, two-and-a-half-month period?

MR. EISENSTAT: Your Honor, if I may object

again, this is way beyond the scope, I think, of the cross examination, what the profits were from buying stock in Kos at the IPO price.

MR. GIDLEY: The cross examination dealt with the market valuation of Niaspan and attempted to attack the expert's opinion on the linkage between Niacor and Niaspan, and the stock market percentage is the heart of this analysis, and again, was an extensive subject of questioning.

JUDGE CHAPPELL: So, your point is you're rehabilitating his direct?

MR. GIDLEY: That's right, in response to the cross examination.

JUDGE CHAPPELL: Overruled.

THE WITNESS: It would have been a very successful investment for someone to have had the IPO stock in March of 1997, and so as of May of 1997, they would have had a substantial return. The percent return is quite good.

BY MR. GIDLEY:

Q. Now, investors that read this document -- and let me direct your attention to page 4. There are the following two sentences at the top of the page:

"Niacin has long been recognized as an effective treatment for lowering total cholesterol,

triglycerides, Lp(a) levels and for raising HDL cholesterol. Several side effects of niacin have curtailed its use, including flushing, itching, gastrointestinal upset and liver toxicity. Niaspan minimizes or avoids many of these side effects," and it continues.

Do you see that?

A. Yes.

Q. And any investor that read Goldman Sachs' investment report on May 9th would have learned about those side effects of niacin. Is that correct?

A. Yes. I think you misspoke. I think it was Salomon Brothers, but yes.

Q. Thank you very much, you're correct.

Directing your attention down at -- let's go on to the next page, page 5.

A. Yes.

Q. "Final labeling and indications for Niaspan have yet to be determined."

Do you see that?

A. Yes, I do.

Q. All right. So, this is as of what date, sir?

A. This is May 9th of 1997.

Q. So, this company was able to go public and investors invested without the labeling and indications

having been finalized for Niaspan. Is that correct?

A. Yes, oh, absolutely.

Q. And it also went public without FDA approval being in hand. Is that correct?

A. It did, yes.

Q. Now, what was the market capitalization of this company in June of 1997?

A. It had gotten to about $400 million.

Q. May I direct your attention to page 8.

A. Yes, I'm here.

Q. And that's Figure 5 on page 8. What is Figure 5?

A. Figure 5 is a pro forma or an estimated set of financials for Kos prepared by Salomon Brothers, and it shows actual fiscal year '95 and '96, picks up calendar year '96 and then carries out the projections through '97, '98, '99 and 2000.

Q. And what is the -- what is the leading drug in the sales projection here for Kos according to the Salomon Brothers U.S. Equity Research unit?

A. The -- by far, the most significant drug is Niaspan with sales projected for about -- of about $20 million in the fourth quarter of 1997, increasing to about $220 million in year 2000.

Q. Let me direct your attention now to page 9,

Valuation. Directing your attention to the first paragraph, how did Salomon Brothers characterize the Kos valuation in May of 1997?

A. It -- it characterized it very well. It described, again, the IPO price being $15 a share on the first day of trading, immediately going up to $22, and now emerging with a -- with what they were calling a value in the $85 to $90 range in three years.

Q. And in the first sentence they wrote, "To date, Kos has led a charmed life as a public company."

Is that what they said?

A. Yes, they are correct, although a short life, but a charmed one.

Q. Directing your attention to the second paragraph, the third sentence reads, "We believe this potential for a compound annual return of 55% over the next three years is attractive, though execution risk still exists for Niaspan since approval has not yet been granted and marketing and manufacturing have not yet commenced."

Do you see that?

A. Yes.

Q. And how would that affect your valuation opinion in this case, sir?

A. Well, it is -- it recognizes the -- the

valuation I did, of course, was for Niacor, and -- but it clearly illustrates that the significant values that pharmaceutical companies and pharmaceutical products have long before they reach the market and overcome all of the regulatory and commercial and manufacturing hurdles that need to be done.

Q. Let me direct your attention now to tab 16, if I could.

Your Honor, I have been handed a note that we are approaching soon our traditional lunch hour and seek guidance from the Court on how much longer we are going to go. We are pretty close to the end of this group of exhibits, but we can break at any time at the Court's pleasure.

JUDGE CHAPPELL: How much redirect do you think you have left?

MR. GIDLEY: I think I have less than an hour after I get through this binder, but I have -- you know, I don't have anything more precise than that.

JUDGE CHAPPELL: Do the parties still anticipate we get out early today?

MR. NIELDS: I'm still predicting that we will finish before 5:30, Your Honor, not quite as much before as I once thought, but I do believe we will be early.

JUDGE CHAPPELL: Then why don't we go ahead and take our lunch break, then. We will recess until 2:30.

(Whereupon, at 1:30 p.m., a lunch recess was taken.)

AFTERNOON SESSION

(2:30 p.m.)

JUDGE CHAPPELL: You may proceed, Mr. Gidley.

MR. GIDLEY: Thank you, Your Honor.

BY MR. GIDLEY:

Q. Good afternoon, Dr. Kerr.

A. Good afternoon.

Q. Sir, I am going to ask you to go back to the redirect binder, tab 16. Sir, we are showing you on the ELMO what appears -- again, it's probably easier to work with the paper copy -- what appears at tab 16 of your binder, sir, SPX 224.

A. I'm there.

Q. And sir, SPX 224 is an Equity Research report at the Dillon Read Company dated May 12, 1997. Do you see that?

A. Yes.

Q. Is this one of the documents that you reviewed in arriving at your opinion, sir?

A. Yes, it is.

Q. Directing your attention to the bullets on page 1, it says, the first bullet, "Kos' lead product is Niaspan."

Do you see that?

A. Yes.

Q. That's the product we have been talking about throughout the day today?

A. Yes.

Q. All right. And the -- that's the lead product of what company?

A. Kos, Kos Pharmaceuticals.

Q. All right. Let me direct your attention within the document now to page 4 -- and by the way, sir, this document bears a date of -- what date, sir?

A. It's May 12th, 1997.

Q. And what kind of document is this?

A. This is an investment analyst -- an investment analysis report from Dillon Read Equity Research.

Q. All right. And directing your attention to the first highlighted sentence on page 4, it appears, "At Kos, management has identified a potential blockbuster by overcoming the troublesome side effects of the only compound that moves all lipid components, including HDL, the good cholesterol, in the proper direction. This compound is niacin."

Do you see that?

A. Yes, I do.

Q. And what product was the equity analyst referring to of Kos?

A. They were speaking about Niaspan.

Q. All right. Directing your attention down within the document, there's mention on page 6 of -- in the yellow highlighted portion of the potential market opportunity in Europe, is there not, sir? Are you there?

A. Yes.

Q. Okay.

A. Yes, I am.

Q. Sir, is there mention on page 6 of potential for sales in Europe?

A. Yes.

Q. And what is that sales potential on page 6?

A. Toward the end of -- toward the end of -- well, I guess it's in the highlighted area there, the analyst is talking about the fact that the model that they're using at the time completely ignores the international sales, although there were sales that would generate licensing fees apparently that they believe for Kos -- for Niaspan in Europe of a few hundred million dollars.

Q. All right. And again, some of that language appears to be language that we saw earlier in this exam, correct?

A. Yes.

Q. In an earlier Dillon Read document?

A. Yes.

Q. Similarly, sir, very briefly on page 8 is a Table 5, Kos Profit and Loss Statement. Do you see that?

A. Yes.

Q. And the Dillon Read Company, have they changed their view about the significance of Niaspan to the future sales potential of Kos at this time?

A. No, not at all. It still is the -- by far the largest and the only really significant product for Kos.

Q. And is albuterol MDI or IS-5-MN generating expected revenues here for fiscal '98 or '99 in this document?

A. No.

Q. Turning your attention to page 9, reference is made to a product called Niaspan. Do you see that?

A. Yes.

Q. And sir, it says, "NDA files Q2 '96. Approval 2H '97."

What is that a reference to?

A. That, again, is -- an NDA is a new drug application filed with the FDA, and it apparently was filed February of '96, and approval, approval was expected, in the second half of 1997.

Q. All right, sir. Let me direct your attention

now, if I could, to tab 17, USX 825.

A. Yes.

Q. This appears to be a research report by the Dillon Read Company. The wording at the very bottom is of poor quality, very poorly legible, but you can make out Dillon Read, can you not, sir?

A. Yes. Yes, I've seen other copies of this, and it's a Dillon Read document or distributed by Dillon Read in any case.

Q. And it bears what date, sir?

A. That's July 1st, 1997.

Q. All right. And what's the title of this research report?

A. The Kos is Clear; Experienced Cholesterol Marketing Warriors Flocking to Kos.

Q. And sir, this document appears to be describing in the second paragraph an effort to assemble a sales force, and I direct your attention to the following language:

"Kos appears to be assembling a cholesterol marketing all star team which bodes well for a successful launch. Experienced, successful cholesterol marketing warriors now fight for Kos. One would think that they would be pretty sure about the potential for Niaspan, to say nothing about the value of future stock

options they would receive before handing in resignation letters to Merck and BMS."

Do you see that?

A. Yes.

Q. And what is the analyst talking about there, what phenomenon?

A. We spoke earlier that at this time Kos was in the process of assembling a sales force. They expected to need a really significant sales force in order to launch Niaspan successfully in the second half of 1997 and were basically starting from scratch, and this is a description of their recruiting effort. At least at this point, Mr. Trepple (phonetic) relates that it is -- it is starting to be successful, as they're attracting salespeople from larger competitors.

Q. Let me direct your attention, if I could, sir, to tab 18, SPX 237. This is a research report dated July 10, 1997. Do you see that?

A. Yes.

Q. And I understand that Mr. Leonard Yaffe, M.D. is with the Montgomery Securities Firm.

A. Yes, I understand that -- know that to be true or was at the time.

Q. Understood, sir. And this would be -- this document would have what relation to the June 17, 1997

agreement between Upsher-Smith and Schering in terms of time?

A. The document itself is somewhat -- is about a month later, but it relates information that's in the market, most of which would have been in the market in June of 1997.

Q. And directing your attention, sir, to the page that's Bates numbered 874.

A. Yes, I have it.

Q. There's reference to at the top of the page CFC formulation of generic albuterol and isosorbide-5-mononitrate. Do you see that?

The top paragraph, just above the yellow highlighted language.

A. Yes, I do, yes.

Q. Then the analyst writes, "However, the majority of sales over the next several years will be derived from Niaspan."

Do you see that?

A. Yes.

Q. Is that your understanding of what market analysts were saying in this time period, July of '97?

A. Oh, absolutely. Yes, absolutely.

Q. And do you see towards the bottom there, there's mention -- or in the middle of the page, do you

see mention of some side effects, including flushing and liver toxicity?

A. Yes. Yes, and again, in the context here, they're talking about the ability of Niaspan, of a sustained release niacin product such as Niaspan, to overcome what had been perceived as adverse side effects of earlier niacin products.

Q. I show you tab 19, sir, a cull-out of testimony by Professor Bresnahan. Were you here for Professor Bresnahan's cross examination?

A. Yes, I was.

Q. And sir, he was asked by counsel:

"Assume that Kos for all intents and purposes was a one product company at that time.

"ANSWER: Okay.

"QUESTION: Niaspan being the product."

I'm skipping.

"QUESTION: Assume the market capitalization of Kos is about $500 million.

"ANSWER: Okay.

"QUESTION: Would that mean that the market valued Niaspan at somewhere in the range of $500 million?

"ANSWER: Yes, if the -- if the -- if they were a one product company for sure, and that was the

only -- that was their only prospect, then I would -- and, you know, Niaspan on a worldwide basis, under those assumptions, the stock market is valuing that prospect at that level."

Do you see that?

A. Yes.

Q. And sir, now that we've surveyed both the Equity Research reports and some of the testimony, sir, how does any of this and the cross examination by Mr. Eisenstat affect your valuation opinion of Niacor versus the Niaspan stock market value?

A. It doesn't change it at all. The -- I think that the performance of Kos and its stock in the market in the early part of 1997 explains well the valuation that I found contemporaneous in -- for Niacor.

Q. I'm going to direct your attention to part of the cross examination from this morning, Dr. Kerr.

Your Honor, I want to make reference to a document that we've asked to treat provisionally in camera, but after consulting with my colleagues, I believe I can conduct my inquiry without clearing the courtroom, and I'll ask my colleague, Mr. Malik, not to publish this on the ELMO if it's agreeable to Your Honor. I think I can ask these questions using a small portion of this document, two sentences, which do not

contain proprietary trade secrets and patent information of Upsher-Smith.

JUDGE CHAPPELL: That will be fine, just ensure the witness understands what the parameters are.

MR. GIDLEY: All right.

BY MR. GIDLEY:

Q. Dr. Kerr, do you understand that in this proceeding we have the ability to go in camera to protect certain trade secrets and other confidential, proprietary data?

A. Yes, I'm aware of that.

Q. And sir, do you understand that companies such as Upsher-Smith have to work, you know, diligently to protect certain proprietary trade secrets? Do you have that understanding?

A. Absolutely, another aspect of their intellectual property.

Q. And sir, you understand that if you feel that an answer you need to give in this courtroom goes into Upsher-Smith's proprietary technology or trade secrets or very detailed information about patents, you should inform the Court before making such an answer, because normally we operate in public session? Do you understand that?

A. Yes, I do.

Q. All right. And you can do that at any time, and I would ask that you simply address the Court and let everyone know before you finish such an answer. Will you do that?

A. Yes, I'll make sure to do that.

Q. Thank you, sir.

I want to direct your attention now to a document that I believe you have up there -- again, we won't put it on the ELMO -- which is a declaration of Ms. Vickie O'Neill. Mr. Eisenstat covered this this morning, I believe.

A. May I?

JUDGE CHAPPELL: Yes.

THE WITNESS: Thank you. Mr. Gidley, I don't see it here, if you could --

MR. GIDLEY: We can try to dig up another copy of the memorandum, just one second -- or the affidavit.

THE WITNESS: I apologize, I don't see the document here.

MR. GIDLEY: Why don't you go ahead and take your chair, and I think that we can --

MR. EISENSTAT: If I may, I have a clean copy, if you would like it.

MR. GIDLEY: Thank you very much.

MR. EISENSTAT: Copy, sir.

THE WITNESS: Thank you, sir.

MR. GIDLEY: Thank you, Mr. Eisenstat.

BY MR. GIDLEY:

Q. Dr. Kerr, I am showing you, with the assistance of Mr. Eisenstat, CX 1731, the declaration of Vickie O'Neill, who was the director at this time of business development and product management for Upsher-Smith Laboratories. Do you have that document?

A. Yes, I do.

Q. And if I may, sir, could I direct your attention to paragraph 15.

A. Yes, I'm at paragraph 15.

Q. And again, I want to direct your attention to a very small portion of this document at the end of paragraph 15.

"We anticipate that Klor Con M will be FDA approvable by the end of this year. When that occurs, the only thing that will prevent Upsher-Smith from introducing Klor Con M to the marketplace is the pendency of this lawsuit."

Do you see that language?

A. Yes.

Q. And sir, this was the -- what's your understanding, is this statement under oath? Is that your understanding of this document?

A. Yes, it's a sworn statement.
Q. All right. And --
A. It's under penalty of perjury.
Q. All right, sir. And it's given on what date?
A. October 23rd, 1996.
Q. And the lawsuit that's being referenced there is what, sir?
A. It's the lawsuit between Key Pharmaceuticals and Upsher-Smith, the patent litigation that involved Schering-Plough and Upsher-Smith.
Q. Is that sometimes referred to as the '743 patent litigation?
A. Yes, that's right.
Q. All right. And the first sentence I read says that Klor Con M will be FDA approvable by the end of this year. Do you see that?
A. Yes, that's right.
Q. All right. Did the -- what does that refer to, the FDA approvable language?
A. It refers to a -- it refers to a process being approvable. It doesn't mean it's going to be approved. It essentially means that the material that would be required for approval would all be in place.
Q. When did Upsher-Smith receive tentative FDA approval for Klor Con M20 approximately, sir?

A. Sometime in early 1997.

Q. All right, approximately March?

A. That's right, I believe.

Q. All right. And final FDA approval occurred when for the M20 product?

A. That occurred at the end of 1998, I believe in November.

Q. All right. Now, sir, the second sentence says, "When that occurs," which is a reference to -- is that to the tentative approval? Is that your understanding?

A. Yes, that seems to refer to that language, yes.

Q. "When that occurs, the only thing that will prevent Upsher-Smith from introducing Klor Con M to the marketplace is the pendency of this lawsuit."

Do you see that?

A. Yes.

Q. And sir, is that consistent with your understanding of what Upsher-Smith was thinking about in terms of coming to market at this time as long as the '743 patent was pending -- lawsuit was pending?

A. Yeah, yes, certainly, I think that the pendency of this lawsuit, as I mentioned yesterday, would prevent Upsher-Smith from having a realistic chance of coming to market.

Q. Could there be economic consequences to

Upsher-Smith that would be adverse had they come to market and the lawsuit not be resolved?

A. Yes, Upsher-Smith and other generic manufacturers in similar situations would be foolhardy to enter the market with the lawsuit pending.

Q. All right. Now, you were also shown yesterday -- and I'm going to be very careful about this question, as well, because these questions are provisional in camera, and I am not going to show them to you. Do you recall yesterday you were asked some questions about in camera -- now in camera court documents from the 1997 time period relating to the '743 litigation? Do you recall that?

A. Yes, I do.

Q. These were shown to you by Mr. Eisenstat?

A. Yes, I recall.

Q. All right. And does anything in -- and I think the two pleadings were documents from that proceeding. Does anything in those documents change your assessment of the economic consequences to Upsher-Smith in this time period of coming to market while the '743 litigation was pending?

A. No. No, those -- and those consequences would be quite adverse.

Q. All right. Sir, you said at one point I think

today and yesterday that you have been involved in this matter since approximately the spring or summer of 2000?

A. Yes.

Q. All right. And we talked both in the cross and in the direct about this business about manufacturing ramp-up at Upsher-Smith. Do you recall that?

A. Yes, I do.

Q. And sir, did you physically see some of that manufacturing ramp-up yourself?

A. Yes, I did.

Q. When was that?

A. Sometime in the summer or fall of 2000, I visited Upsher-Smith, and at the time there was construction going on to expand their warehouse facilities and their production operations in anticipation of being able to enter the market with Klor Con M10 and M20 in September 2001.

Q. All right. Let me ask you now to set aside, if you would, the redirect binder that we gave you.

A. May I return the in camera document?

Q. Please do, and I appreciate you remembering that.

JUDGE CHAPPELL: Yes, thank you.

MR. GIDLEY: Thank you again, Mr. Eisenstat.

BY MR. GIDLEY:

Q. Dr. Kerr, yesterday towards the beginning of the cross examination you were asked about some safety and efficacy characteristics of the K-Dur product line. Do you recall that?

A. Yes.

Q. Do you hold yourself out as having expert knowledge in the actual underlying medical or pharmaceutical knowledge of the safety and efficacy of the K-Dur product line?

A. No, not at all.

Q. Do you hold yourself out as being capable of evaluating the safety or efficacy of Niacor-SR?

A. No, certainly not.

Q. Do you hold yourself as being capable of evaluating from a medical standpoint the safety and efficacy of Niaspan?

A. No.

Q. Now, you have chosen in this case to compare Niacor to Niaspan. Is that correct?

A. Yes.

Q. Now, do you believe that they are a perfect 100 percent -- strike that.

What's your general sense of how comparable they are?

A. Well, they work quite comparable, the product works -- and the evidence of that is the perceptions of the people in the marketplace at the time, and that's really what I rely upon, the people who know about these -- the technical sides of these products. That's what I have to do to be a business analyst.

Q. Did folks at Upsher-Smith closely track the progress of the Kos Pharmaceuticals IPO?

A. Oh, yes, yes, certainly.

Q. Can you give me an example?

A. I believe Mr. Halvorsen testified that he had it on his -- on his desktop, and it popped up as it came along. Also, of course, we know that they were involved in a cross-license agreement with Kos in 1997, which, again, tells us that they had a lot of knowledge about Kos and its Niaspan product. And there's documents -- the record is full of references, contemporaneous references that Upsher-Smith was examining closely the progress of Niaspan because they were so intent themselves upon introducing a product which was a direct competitor of Niaspan's.

Q. How about Pierre Fabre, did they know anything about Kos, do you recall?

A. Yes, that was the belief of the Upsher people who entered some discussions with Pierre Fabre in the

spring of 1997. They -- it was clear that Pierre Fabre knew about the Niaspan products, knew about the market, and they believed that that was as a result of discussions that they had with Kos about the prospect of doing some sort of a venture with Kos.

Q. All right. Now, I believe Mr. Eisenstat asked you a question or two about whether K-Dur reduced certain side effects of potassium therapy. Do you recall that?

A. Yes.

Q. Now, were you testifying from a basis of medical knowledge or pharmaceutical knowledge when you gave those answers?

A. No. No, again -- no, not my knowledge of the technical side or the medical side. It's my perception of the commercial implications of those -- of whatever the technical matters are that relate to the products.

Q. The statements that you made in your report came from what source?

A. They came from -- well, primarily in that instance they came from Schering documents, internal Schering documents, marketing documents that talked about the marketing message that they had in place for their products at the time.

Q. Have you reviewed or are you aware of, sir, any

controlled studies that compare Klor Con potassium versus K-Dur potassium -- and I'm talking about the wax matrix Klor Con line -- in terms of patient compliance?

A. No, no, I'm not.

Q. Another quote that came out of your report during Mr. Eisenstat's examination, let me try to locate it, was a quote that Mr. Eisenstat read from your report that had to do with the Bresnahan test and prong one. Do you recall that?

A. Yes.

Q. It was early in the examination.

A. Yes, I do remember.

Q. And that came out of the Kerr expert report. Is that correct?

A. Yes, it did.

Q. All right.

Excuse me just one second.

We'll retrieve your report, but I think I can keep things going here.

Sir, in your expert report, did you critique the three-prong Bresnahan test?

A. Yes, I did.

Q. All right. Can you state briefly or summarize briefly the point that you were making in your report about prong one of the Bresnahan test?

A. Well, prong one of the Bresnahan test had to do with monopoly power, and what I observed in Mr. Bresnahan's analysis was that, first of all, he defined monopoly power as being based on a single product market, the single product being K-Dur 20, and I observed that if in a generic/branded situation in the pharmaceuticals industry, if a branded product -- if you have a single-product product market and you further do what Professor Bresnahan did, which was to define the product in terms of whether the price was higher than it would be if there was entry, instead of looking at what is more normally done in -- by economists in looking at market power, and that is looking at profitability, you will certainly be able to conclude, as he did, that Schering had monopoly power, but it's based on the wrong definition of monopoly power.

But if you did it that way, that test would be meaningless, because every instance of a generic and a branded producer involved in a patent lawsuit -- and that's what you're trying to test for -- would by definition have monopoly power, incorrectly so.

Q. And I've put on the screen the entire quote, and I'd like to just read it into the record for our paper transcript at page 30, sir, and I'm going to

start -- it's the paragraph that begins, "The first prong."

MR. EISENSTAT: Your Honor, this document is not in evidence, and I would object to him just reading documents that are not in evidence into the record.

MR. GIDLEY: Your Honor, I'm invoking the rule of completeness. I waited my turn, about a day and a half, and I simply wanted to put the full context of the sentences that have already been read by this lawyer into the record.

JUDGE CHAPPELL: So, first of all, the document is not in evidence.

MR. GIDLEY: That's correct, Your Honor, and I'm not seeking the admission of this exhibit. I'm seeking to provide the correct context for a question that was quoted from this passage by complaint counsel.

MR. EISENSTAT: He's got the author on the stand, Your Honor, and if he wants to ask the author -- and I believe he already has -- what the context is, he's already given that and can do that, but I object to him simply reading a passage from a document that is not in evidence into the record. He is not impeaching the witness.

MR. GIDLEY: Your Honor, all we want to do is make sure that the snippet that was read by complaint

counsel from this very paragraph sits in the record with the complete paragraph. I don't want anything more than that, and I'm simply going to then ask a final question, which is to reference the answer he just gave to this language to make sure that we have a clean record.

JUDGE CHAPPELL: So, you are under the rule of optional completeness trying to connect the dots, complete the circle, based on what complaint counsel brought up in cross?

MR. GIDLEY: That's right, Your Honor. We never would move the admission of this document, and we have not previously quoted from this document. It only came up during cross examination.

MR. EISENSTAT: And the only reason I quoted from it, Your Honor, is I asked the witness the same questions without the document in front of him. He gave a different answer. I pulled this out merely to impeach him on the specific paragraph that I read to him.

JUDGE CHAPPELL: Well, if a document is used, the other side has the right to rebut that use under the rule, under the optional completeness rule. You have the right to address that on recross if necessary. So, the objection is overruled.

MR. GIDLEY: I will be brief, Your Honor, thank you.

BY MR. GIDLEY:

Q. The paragraph reads, "The first prong of Complaint Counsel's test asks whether the pioneer has market power. While this would seem to be a reasonable question, in the context it is proposed, it is not. It can have only one answer. If a pioneer's patent did not provide any market power, there would be no reason for a generic to challenge the patent. There would be no patent litigation and, it is unlikely that the antitrust authorities would care, because the profits on the product would likely be too low to be subject to antitrust enforcement solutions."

The final sentence says, "Therefore, the first prong of the test is irrelevant."

Do you see that, sir?

A. Yes, I do.

Q. Was that paragraph a reference to the Bresnahan test?

A. Yes, it was. It was a comment on the first prong of the Bresnahan test, yes.

Q. And the answers you gave me before we put this on the ELMO, did they relate to this passage, sir?

A. Yes, they did.

Q. At another point in the cross examination, Mr. Eisenstat asked you to make a numeric calculation you did not make in your report. Do you recall that? This is a calculation that compared two revenue figures, and you computed at his request a comparison of those two numbers at 74-75 percent. Do you recall doing that during cross examination?

A. Yes, I do.

Q. And again, just so that I have the context for the question and the answer, the two numbers, $260 million and $350 million, that Mr. Eisenstat was asking you about came from your report. Is that correct, sir?

A. Yes. Yes, they did.

Q. All right.

A. They appear in the report.

MR. EISENSTAT: Again, Your Honor, I don't see any completeness issue here, and I'm objecting to him just putting the report up on the screen. It's not in -- it's not in evidence.

MR. GIDLEY: Your Honor, I am not seeking its admission. I'm simply making sure that I can reference with the witness his report and Mr. Eisenstat's question so that I can ask him some follow-up questions.

JUDGE CHAPPELL: Well, the line of questioning

appears to be going -- relating back to your questions of the witness, so I'll overrule the objection.

BY MR. GIDLEY:

Q. Dr. Kerr, Mr. Eisenstat asked you to compare those two numbers in the final sentence on that page. Is that correct?

A. He did. I think he actually did the comparison.

Q. Oh, and he gave you the result?

A. Yes, he did.

Q. I appreciate the qualification.

Now, sir, have you done an extensive analysis of the product market that would be applicable in your mind for this case?

A. Well, I haven't defined the relevant market, but I referred there to the potassium chloride market.

Q. All right. And sir, the figure for K-Dur of $260 million, does that include both K-Dur 10 and K-Dur 20?

A. Oh, absolutely it does, yes.

Q. All right. Now, if I might direct you to the following --

May I approach, Your Honor?

JUDGE CHAPPELL: Yes.

MR. GIDLEY: Dr. Kerr.

THE WITNESS: Thank you.

MR. GIDLEY: Your Honor.

BY MR. GIDLEY:

Q. Dr. Kerr, I'm handing you a group of exhibits, several of which I may refer to briefly. May I direct your attention to tab 1, that's the Bresnahan test. Do you recall that from your direct?

A. Yes, I do.

Q. Under the Bresnahan test, prong one, "Does the patent holder have monopoly power," when does Dr. Bresnahan measure that? At what date under the Bresnahan test did he evaluate monopoly power?

A. Oh, he testified that -- and I guess it's in his report, too -- that the proper time to evaluate monopoly power would have been in the spring of 1997, around June of 1997 when the agreement was entered into.

Q. And sir, were you in the courtroom when that testimony was given?

A. Yes.

Q. And I show you on the next tab, which is taken from the Bresnahan cross examination, the yellow highlight starting on page 659.

"QUESTION: And I take it, sir, for prong one to be met, the patent holder, here Schering-Plough,

would have to have monopoly power. Isn't that correct?"

A. Yes it is.

Q. Let me read the whole passage.

"QUESTION: And I take it, sir, for prong one to be met and the patent holder, here Schering-Plough, would have to have monopoly power. Isn't that correct?

"ANSWER: For it to be met, yes.

"QUESTION: And we measure these three prongs in terms of the time period as of June 1997, the date of the June 1997 agreement between Upsher-Smith and Schering-Plough, do we not?

"ANSWER: I'm sorry, I don't understand -- I don't fully understand that. "

Then skipping down:

"ANSWER: I don't fully know what you mean by measure a prong. I mean, the test is applied to monopoly power as of that date.

"QUESTION: As of June 17, 1997, correct?

"ANSWER: Yes."

Skipping down to 661:

"QUESTION: And just so I understand, let's go back to the first prong or the first part.

"If neither Upsher-Smith nor Schering-Plough was a monopolist, prong one would not be satisfied if

we measured that as of June 17, 1997. Isn't that correct?

"ANSWER: That's correct."

Do you recall that testimony in this courtroom?

A. Yes, I do.

Q. Now, sir, very briefly, what is your understanding of the market share of Schering-Plough in the potassium chloride market in approximately June 1997?

A. Schering had well less share, probably they would be in about the 30 percent range, in June of 1997.

Q. The calculation that Mr. Eisenstat gave you was expressed in terms of sales dollars. In your view, is that the right way to look at the definition of relevant market and market power and market share for potassium chloride?

A. Although I have not done the analysis myself, I don't believe it is. There are problems with the data in pharmaceuticals when you look at dollar shares. Also, keep in mind the Bresnahan -- the number in my report was a 2000 number, not a June 1997 number. And there are a number of other reasons having to do with the way the products are marketed that would tell me that measuring in terms of units was a much more

appropriate way to do it.

Q. In terms of dollars, why would there be data inconsistencies? What do you mean by that?

A. The standard -- the standard data that is available publicly in -- for sales in the market for pharmaceuticals comes from a company called IMS. There are some other competitors of theirs, but they're primarily IMS data, and that data is problematic in many instances, because it doesn't include the entire market. It therefore -- and the portion of the market that's not included tends to be a lower-priced portion of the market and the prices that come out of that data overstated.

In addition, the information that comes out of IMS does not include things such as rebates, discounts and so forth. The net result is it tends to overstate the share of -- typically of larger companies.

Q. I see. And sir, in general, in pharmaceuticals, when does the demand begin typically for a pharmaceutical product?

A. The demand begins for a pharmaceutical product such as this with a prescription.

Q. That would be in the doctor's office?

A. Absolutely.

Q. All right, let's set that aside.

A. Or a hospital I suppose.

Q. You were asked a series of questions yesterday about something called PK or pharmacokinetic studies. Do you recall that?

A. Yes, I do.

Q. Now, you're not an expert in the conduct of pharmacokinetic studies, are you, sir?

A. No, I'm not.

Q. All right. You've never yourself conducted a PK study. Is that correct?

A. Certainly not.

Q. All right. Do you have an understanding about whether PK studies in the context of this case are easy or difficult?

A. Yes, I'm aware of testimony in the record that these are -- in the context of obtaining FDA approval, the PK studies are a trivial -- maybe "trivial" is too strong a word, but certainly an easy -- an easy process.

MR. GIDLEY: May I approach, Your Honor?

JUDGE CHAPPELL: Yes.

BY MR. GIDLEY:

Q. Dr. Kerr, I direct your attention to tab 1 of the PK book you've been handed. This is an expert -- an excerpt of testimony from Dr. Levy. Were you here

for that testimony?

MR. EISENSTAT: Your Honor, if I may object, this -- this is a -- while he appears merely to be giving the expert documents, this seems to be classic leading. He asks the man a question, and then he gives the book and points to answers in the book and asks the witness to adopt them. This whole line of questioning is simply leading this witness from one answer to the other.

MR. GIDLEY: May I respond, Your Honor?

JUDGE CHAPPELL: Yes.

MR. GIDLEY: We had about 30 minutes of testimony yesterday from snippets of various arcane, highly technical documents, most of which weren't published or shown or confronted to the actual business people, like Mr. Halvorsen or Schering-Plough executives, who these documents would have been relevant to, so complaint counsel published them to this witness, knowing his limitations, and elicited a string of testimony simply of reading the documents into the record.

I simply want on redirect to clarify the record and address the point. My unit on this is brief, but I do not see how complaint counsel can open the door and then not have any redirect.

MR. EISENSTAT: He can ask the man what he would rely on, and if he can cite to a particular witness, then he can call it up, but for him to hand the man answers highlighted in testimony and direct him to those answers, that seems to be classic leading, Your Honor. He's not only suggesting the answers, he's highlighting it in the testimony and then handing it to the witness.

MR. GIDLEY: Your Honor, I don't want to be contentious. Let me simply make the following point. Would you set the book aside, sir? I can lay a brief foundation. I don't believe that I'm leading this witness in any way more so than any of the experts put on by complaint counsel, but I'm happy to establish a foundation and then proceed from there. Would that be agreeable to the Court?

JUDGE CHAPPELL: I didn't object.

Do you want to withdraw your objection?

MR. EISENSTAT: No, Your Honor, I do not.

JUDGE CHAPPELL: Well, I am going to allow him to question the witness on areas that were brought up in cross exam. This is redirect. That's what it's for. I agree with you that I'm not going to allow Mr. Gidley to hand the witness something, have him read it, and then have the witness just say, yeah, that makes my

point. I agree that that's leading. So, you need to change your tack a little bit.

MR. GIDLEY: Thank you, Your Honor, understood.

BY MR. GIDLEY:

Q. Dr. Kerr, do you remember any testimony in this case about PK studies being easy?

A. Yes, I do.

Q. Could you give me an example?

A. I believe Dr. Levy testified about it. He was an expert earlier in the case. And several of the Schering executives testified about them. In particular, I recall Mr. Lauda.

Q. What do you recall about Dr. Nelson Levy? What did he say about PK studies?

A. The gist of his testimony was that they were easy, and, in fact, they might even be trivial. Maybe "trivial" is the right word.

Q. Do you recall his exact words?

A. I think he testified about them being as easy as falling off a log.

Q. And that being a reference to PK studies, sir?

A. Yes, yes.

Q. All right. And you also mentioned Mr. Lauda. What company is he with?

A. Mr. Lauda is with Schering or with Key, I'm

not -- but with Schering -- a Schering organization.

Q. Do you recall what Mr. Lauda said about PK studies?

A. Yes, that -- that they were relatively easy.

Q. All right. Do you have a distinction in your mind or have you gained an understanding about PK studies as contrasted with other drug studies that -- from your review of the documents in this case?

A. Yes, I have. They -- and they appear to be done in a -- are relatively easy compared to the rest of the fairly onerous process that drugs like this have to go through to get FDA approval.

Q. Is that easy in terms of time or number of patients or cost? What do you mean by "easy"?

A. I -- my understanding is that it's all three. They don't take very long, they don't require a great many patients, and therefore, they don't cost very much relative to some of the other tests which are massive.

Q. Dr. Kerr, you were asked a series of questions about your economic valuation, and let me reference that for you. We are going through a lot of documents. Could you take out your direct examination binder?

A. Yes.

Q. May I direct your attention, sir, to tab 15, USX 1601.

A. Yes, I have it.

Q. All right. And do you recall Mr. Eisenstat asking you some questions about your valuation as it appears on 1601 yesterday?

A. Yes, I do.

Q. All right. My recollection is he asked you a question something along these lines. First, one of the premises of his questions was were the numbers on this page your actual own independent analysis. What's your view of that, sir?

A. Well, the analysis is my own independent analysis certainly. I use information from a number of other places, and that information comes -- depending on what information it is, it can come from three or four different sources.

Q. All right, sir. The Discount Rate line, it says, "Discounted cash flow at 25 percent."

A. Yes.

Q. Do you see that?

A. Yes.

Q. Does that line appear in the Schering-Plough board of directors presentation book?

A. No. No, it doesn't. It wouldn't. They used a discount rate somewhere in the range of 13 percent.

Q. Who created this line of 25 percent?

A. I did.

Q. How does 25 percent compare against other discount rates and standard valuations that you do in intellectual property?

A. It's at the high end of any discount rate that you would normally see in this kind of an analysis. That's why I chose it. I mean, I mentioned before that I was trying to be conservative in selecting the discount rate, and that's why I did that.

Q. All right. Now, there was questioning about some of these numbers, and they came from I think Mr. Audibert. Was that the thrust of the cross examination?

A. Yes.

Q. Do you recall that testimony?

A. That's right.

Q. All right, sir. And at one point you were asked a question something to the effect of if someone were to take a risk discount and multiply all of these numbers by 50 percent, in other words, it's a coin flip whether Niacor-SR works out or not, you know, would that be a valid way to change the analysis, and sir, I'd like your candid reaction to that.

A. Yes, I think the question was would it be appropriate to take -- to do an expected value

calculation. Remember, that was an -- that calculation was something that I used for other purposes in the probability analysis. The answer to that is absolutely not. It would not be appropriate to use an expected value calculation for any of the numbers in here, and the reason for that is that this analysis is intended primarily to deal with the riskiness of situations that the -- that affect the cash flows that are in question, and it explicitly takes that into account, that risk is taken into account using the discount rates.

Q. And sir, can you point on this spreadsheet, which is a lot of numbers for us lawyers, where you did that?

A. Well, it would be the bottom line, the discounted cash flow line, where I discount the nominal flows by a 25 percent factor for the entire period, taking into account the risk that -- taking into account, as I mentioned yesterday, the time value of money and the risk that -- and a risk factor.

Q. And what risks are in that risk factor?

A. Everything from -- from the risk of war to the risk of market -- markets and market failure of various kinds and --

Q. You were --

A. -- risk related to the product market.

Q. You were asked a series of questions about Mr. Audibert's assumptions, and there was a series of questions that followed. Where do you independently evaluate his assumptions? How does -- how do his numbers go to being your numbers, sir, in essence?

A. What I did was I -- in order to do a present value analysis, as I've done here, you need to determine the cash flows, and when I found the Schering-Plough board presentation and ultimately the building blocks of that -- of the numbers in that presentation, I determined that that was the most consistent set of information available.

What I did before I used it was I went through a number of different analyses, which I think I previously described, including the Kos analysis, looking at public information on the size of the relevant market for this analysis, not a relevant antitrust market necessarily, but that is the niacin market, the cholesterol market in the United States and overseas, and all of that evaluation told me that the numbers that Schering was using, that the executives at Schering were using to illustrate the value of this product during the time they were presenting it to the board present -- to the Schering-Plough board, were quite reasonable.

The market shares that they were using were well below the market shares that people were projecting for Kos' Niaspan in the United States. The dollar amount of their sales were well below the dollar amount of sales that was being projected for Niaspan. That's despite the fact that the foreign cholesterol-reducing market, of which this is a part, is much larger than the domestic cholesterol-reducing market.

Q. Sir, you were here for the Bresnahan cross examination?

A. Yes, I was.

Q. Do you recall Dr. Bresnahan being asked about the numbers that appeared in Schering-Plough's presentation, the exact numbers that appear above the lines that you have?

A. Yes, I do.

Q. For instance, do you recall his testimony about expected revenues and cost of goods sold and so forth?

A. Yes. Yes, I do.

Q. Did Dr. Bresnahan have different values for these dates and years and lines?

A. No, no, I think -- to the contrary, he testified that he had no reason to disbelieve any of these numbers.

MR. GIDLEY: Your Honor, I have one brief in camera unit, and I think it takes less than five minutes, and I'm prepared to do that now.

JUDGE CHAPPELL: Okay, I'll have to ask the public to leave the courtroom as we enter in camera session.

(The in camera testimony continued in Volume 28, Part 2, Pages 7049 through 7051, then resumed as follows.)

JUDGE CHAPPELL: Thank you, Ms. Bokat.

You may continue.

MS. BOKAT: You're welcome, Your Honor.

MR. GIDLEY: Thank you, Your Honor.

BY MR. GIDLEY:

Q. Dr. Kerr, I want to reference some testimony this morning that dealt with Moreton. Do you remember that?

A. Yes, I do.

Q. We will have that up on the ELMO in just a second, but while we're running through these exhibits, could you retrieve a copy of CX 841 from your large and growing stack?

A. 841?

Q. Yes. Thank you very much.

You will recall, sir, that you were asked a

prolonged series of questions quoting portions of this document. Is that correct?

A. Yes.

Q. And there was particular emphasis by Mr. Eisenstat on the companies that did not express interest in Niacor-SR. Do you recall that testimony this morning?

A. Yes, I do.

Q. All right. Are you generally familiar with the marketing effort that Upsher-Smith made in Europe for Niacor-SR in the first six months of 1997?

A. Yes.

Q. And sir, having gone through this document in tedious detail, apparently with particular reference to portions complaint counsel want to focus on, sir, does that change your opinion of the value of Niacor-SR in any way?

A. No, no, not at all. I've -- this document is one of the things that I looked at in doing my original -- well, it's a document that I rely on to demonstrate the interest of the potential partners in the non-NAFTA markets for Upsher's Niacor product.

Q. Why doesn't it concern you that so many companies closed the door on Mr. Pettit in this time period?

A. Because I'm familiar with the way these kinds of marketing agreements are entered into and the kinds of efforts that people make to do marketing. This is how it's done. Mr. Pettit did what would normally be done in this case. He kind of went out and sent out a mass mailing to everyone who was a potential -- who might potentially be a partner, and you can see from the list that it includes virtually everybody who is a pharmaceutical manufacturer or distributor outside of the United States, primarily in Europe.

The net -- the result of these kinds of mass mailings is often a very small percentage reply, and I remember Mr. Patel of Kos talking about very low percentage returns on something like this, and I've also -- we've also heard from the director of in-licensing at Eli Lilly through an LES function that their rule of thumb is the number is relatively low, certainly in the single digits.

Q. When you say single digits, what do you mean, in terms of percent response?

A. In terms of percent response, yes. The fact that you send out 50 letters, cold letters, would -- with a very small amount of information almost guarantees that you're going to get back a relatively small response. The next step, though, is, of course,

to then go out and follow up on anyone who does open the door, who does -- who does express any response. So, what we ended up with is not -- is certainly not a surprising response rate.

In fact, by the time that the agreement was signed in June of 1997, as we've seen, there were four or five companies still interested in Niacor, and several of them continued to express that interest after the signing of the licensing agreement in June of 1997.

Q. Now, was there aggressive pursuit by Upsher-Smith of licenses after June 18, 1997?

A. Well, no, to the contrary. Once the agreement was signed with Schering, there was no need to do that, although Schering did have the ability to sublicense to anyone outside of the NAFTA market, and in a number of instances, Upsher referred people who were interested in Niacor to Schering to try to talk about sublicensing.

Q. And sir, did Upsher-Smith at this time have a sales or marketing organization in Europe?

A. No, they didn't.

Q. And at this time, did Schering-Plough have sales offices in Europe?

A. Yes. Yes, they were -- they had a great deal

of sales in Europe.

Q. Now, these companies -- forgive me.

These companies that are in CX 841, did all of these companies have sales offices and marketing arms throughout every European countries, or were some of these more local?

A. Yeah, well, some of them -- some of them were localized. The -- these companies run the gamut from single-company pharmaceutical -- single-country pharmaceutical operations to, you know, large multinationals who have operations in every country in Europe and likely every country in Africa, Asia and North America as well.

Q. And sir, you ran through some examples like that with Mr. Eisenstat, is that correct, of the localized firms?

A. Yes. Yes, Dr. Esteve is a smaller firm. Lacer is a smaller firm. Those both have operations primarily in the Iberian countries.

Q. And from the transaction cost standpoint, is it more efficient to have a single worldwide non-NAFTA license than to go out and on a piecemeal basis line up European marketing partners?

A. Yes, it would generally be preferred to have a single partner, one who had a substantial marketing

presence in all of the relevant territories.

Q. Okay.

Just one second.

(Counsel conferring.)

MR. GIDLEY: Thank you, Your Honor, I appreciate the indulgence.

BY MR. GIDLEY:

Q. By the way, Dr. Kerr, have you ever personally sold a residence, a home, a house?

A. Yes, I have, a number of times.

Q. Have you ever had the experience, like some of us, of putting it out there and on Sundays, members of the public come through your home and take a look at your house while it's on the market?

A. Unfortunately, I've never had to do that, but I've gone through the process with agents. It works well.

Q. All right. And is it your experience that everyone who comes through the house makes an offer?

A. No. No, hardly.

Q. All right. And sir, the fact that people come through the house and don't make offers, does that mean that the house you're living in at that time is worthless?

A. No, not at all.

Q. I see. And once you sell a house, have you ever tried to sell the house twice, the same house?

MR. EISENSTAT: Your Honor, may I object? This is way beyond the scope of cross, selling houses, getting people to come in on Sundays to look at them.

MR. GIDLEY: Your Honor, this witness has a great deal of experience in the sales and marketing and alienation of intellectual property. I'm making a simple analogy in response to cross examination, which went on for 30 or 45 minutes reading into the record companies expressing no interest. I'm happy in the next question to link it up, if necessary or need be for the record.

JUDGE CHAPPELL: It is necessary and it does need to be, so I'm overruling at this time, but I need the connection now.

MR. GIDLEY: Let's do it, Your Honor.

BY MR. GIDLEY:

Q. Dr. Kerr, do you see any similarity between the simple example I gave you of a house and the marketing effort by Mr. Pettit on behalf of Upsher-Smith with respect to Niacor-SR intellectual property rights in the first half of 1997?

A. Certainly, yes. The -- the analogy to selling a house is very -- is a good one for selling

intellectual property or setting up licensing arrangements in intellectual property. You go out and you try to attract people to your house, and you try to get them to come through, and one out of ten, one out of 20, one out of 30 is interested. Ultimately you hope that one will be interested enough to buy the house.

And the same thing happens when you're doing licensing transactions. You make known that -- your ability to provide intellectual property, and you hope that you do that in a very focused way, in as focused a way as you can, to people who might have some reason, valid reason, for taking the license and for selling -- and for taking on the product and exploiting the intellectual property, but dozens, perhaps hundreds of your contacts don't work. Eventually, a handful, five, ten, twelve come back in and do express an interest, and you sit down and you talk seriously maybe with two or three.

Again, you only need one, but -- and if you're the seller, you hope that there's two or three out there at the end who are bidding against each other, but it's a very good analogy. That's exactly how the process works, and that's why I wasn't surprised to look at the Moreton record and see that 50-60 contacts

were made, ultimately generating interest among five or six contacts.

Q. Now, you were shown a serious of memos, sort of trip reports, meeting reports, authored by Ms. O'Neill. Are you familiar with those trip reports as they relate to European Niacor-SR licensing efforts?

A. Yes.

Q. And sir, in those European trips, did Mr. Troup attend those meetings?

A. No, he did not. They occurred -- the European meetings occurred in early June of 1997. Mr. Troup was involved in trying to end the patent litigation between Schering and Upsher. He was stuck in the United States and didn't attend. I don't believe he attended any of the meetings with the European companies. Ms. O'Neill and Mr. Halvorsen attended those meetings.

Q. Dr. Kerr, I'm going to ask you just a few questions about your litigation model. Do you recall cross examination on your litigation model?

A. Yes, I do.

Q. And you remember that analysis and the decision tree and so forth, correct?

A. Yes, I do.

Q. All right, the gist of several questions involved the fact that your PENTA database is built

around patent damages cases. Is that correct?

A. Yes, it is.

Q. All right. Sir, have you done any pressure testing to determine whether or not general patent or IP cases, with or without damages, would alter the results that you obtained using your data?

A. Well, pressure testing is a good phrase, but what we did is we did look at other sources, and based on the other sources, we concluded that there was no reason to use anything other than our patent database for the information that we obtained.

Q. And that pressure testing, what was the data for that?

A. It varied. In one instance, we -- well, several things we did. One of the -- one of the data pieces that we took out of the patent database, you may recall, was the amount of time that it takes to get from an appealable ruling in District Court to a decision by the Federal Circuit, and at the time we did this analysis, we had data through 1998, I believe, and there were only -- and the time was 19 months, the average time was 19 months or one year, seven months.

We did two things. One, we looked at the patent database again after inputting subsequent years of data, which is now -- it's now complete through

2001, and the period goes from 19 to 20 months. We also looked at -- you may recall, I mentioned another database that we used, the -- which is based on information from the Administrative Office of the Federal Courts, which covers all patent cases, not merely patent cases which involve decisions leading to a damage award, and in -- in looking at that data, we determined that the period was 18 and a half months for the entire population, and therefore, I concluded that the damage cases are no different than the general population of patent cases that are decided and taken to appeal.

Q. Sir, you were asked a series of questions yesterday about whether your 10 percent summary judgment assumption was a reasonable one. Have you done any sensitivity analysis of that assumption of your decision tree analysis model?

A. Yes, we've done sensitivity analyses of almost all of the pieces of that model. The 10 percent in particular we've done a number of different versions. In one case, we doubled the percentage from 10 to 20 percent. In another, we -- and we've done other things, too, 13, 14, 15 percent.

Q. All right. And how does that affect the outcome?

A. In a -- in a nonsignificant way, so we stuck with the 10 percent. The 20 percent number, which was the most extreme, as I recall, moved the time in a month to January 2003. You may recall that the average date was February 2003. If you double to 20 percent the summary judgment percentage, it comes back to January 2003.

Q. Sir, different set of questions Mr. Eisenstat asked you. These had to do with basically whether or not anyone can truly know what would have happened in a world that didn't occur. In other words, no one really knows whether or not what would have actually happened in the '743 trial with that judge, with these players, no one really knows that alternative world.

Do you recall that kind of questioning?

A. Yes.

Q. Sir, does that lead you to believe that you can't estimate possible litigation outcomes?

A. No. No, not at all.

Q. Is it done routinely in this country, decision tree analysis of litigation?

A. Oh, yes, it's applied all the time, either formally with a decision tree analysis or informally, or less formally with other quantitative methods.

Q. And your analysis wasn't created for this

litigation.

A. Oh, no.

Q. Your methodology, that is.

A. It's used all the time.

Q. Finally, there was just a broad range of questions that I'm going to call due diligence questions, questions in the form of, you know, if you were at Schering and you saw this document, wouldn't you be interested in that fact? Do you understand the general tone of that line of questioning?

A. Yes, I do.

Q. All right. This isn't really my issue, but I just want to ask one or two cleanup questions here.

Now, sir, do you believe that the level of due diligence by Schering-Plough is important to assessing the Bresnahan three-prong test?

A. It doesn't appear to be a significant issue in the Bresnahan test, no.

Q. In fact, does the Bresnahan test make any reference to due diligence in the three prongs?

A. No, not at all, and I don't see how the due diligence would fit into the analysis of any piece of the Bresnahan test.

Q. Now, sir, if we were to create in this courtroom or at a later date as a policy matter a rule

where we imposed an objective standard of due diligence for multidimensional litigation settlements, what do you think the effects of that would be?

MR. EISENSTAT: Your Honor, I object that we're now going way beyond his original report or his testimony or anything. He's never offered opinions in this area before, and I object that we're going way beyond what's appropriate for him to testify about.

MR. GIDLEY: May I address that, Your Honor?

This witness reviewed the Bresnahan test, and in connection with reviewing the Bresnahan test made extensive critique. We're not handing Your Honor the report, but both in the direct and extensively in cross, probably an hour and a half, two hours, three hours yesterday, tediously crawling through documents, the issue of due diligence was suggested.

I think this witness with his expertise can be confronted with the net effect of all of those questions, without putting the Court and counsel and the witness and everyone through going through those documents, with whether or not the import of those documents changes his view of this litigation and his conclusion that is reflected in his report.

MR. EISENSTAT: Your Honor, he just -- he gave no opinions on objective rules of due diligence at any

time, and to get -- to go into new opinions at this time is simply improper.

MR. GIDLEY: I'm very sensitive to this point, Your Honor, but my recollection of the report is that Dr. Kerr expressly opined that complaint counsel's policy rule would chill intellectual property transfers. I will try to get the page cite if that would assist complaint counsel.

JUDGE CHAPPELL: Well, let's just pause, and you two look at the report and let me know what you decide. It's either in there or it's not in there.

(Pause in the proceedings.)

MR. GIDLEY: Your Honor, the passage in question that I was remembering, Mr. Eisenstat, appears at pages 30 to 31. The entire passage is about the Bresnahan test and the chilling effect of the three-part test and in particular the fact that parts of the test are circular, and basically any patent infringement settlement involving a branded pharmaceutical manufacturer would flunk the first two tests, and the third test doesn't have true significance for policy makers, except to chill settlements, and the quote that I would direct the Court's attention to, kind of a wind-up, appears in the middle of page 31, Your Honor, and I would read a

sentence of that if it would not violate our general rule of not reading the report into the record. I leave that up to Mr. Eisenstat and to His Honor.

MR. EISENSTAT: I still don't see anything in here about objective -- rules of objective due diligence, whatever the question was about, so if you could point me to the --

MR. GIDLEY: I am very inclined to read it, Your Honor. If there is no objection, I would read three sentences that appear in the middle of page --

MR. EISENSTAT: Why don't you point them out to me instead of reading?

JUDGE CHAPPELL: What you are reading and what you're saying now is not evidence.

MR. GIDLEY: Fine, just for the sake of this argument, the quote that I would direct counsel to is the following quote:

"The first two parts of the Bresnahan test are meaningless and the application of the third part is incorrect. Virtually any settlement between a generic and a pioneer that includes time off the patent and one or more side deals would be likely to fail such a test in the view of an analyst using hindsight to second-guess the settlement. A test that no one can pass is useless."

That passage about hindsight and second-guessing goes directly to this opinion. This is not a new opinion.

MR. EISENSTAT: I don't hear anything in there, Your Honor, about objective due diligence, which is what I heard him ask about just a moment ago.

JUDGE CHAPPELL: Nor do I. I sustain the objection. If you want, you can attempt to finetune it without asking for a due diligence opinion.

MR. GIDLEY: Very good, Your Honor.

Your Honor, could I have one minute to confer with counsel? I'm very close to the end of this redirect.

JUDGE CHAPPELL: Yes.

(Counsel conferring.)

BY MR. GIDLEY:

Q. Dr. Kerr, yesterday, Mr. Eisenstat asked you the following question, basically it was this: Sir, given the fact that these licenses go on in time, why is it that Schering-Plough even today might not market Niacor-SR? Why don't they take it off -- the import of it was, if you will, why don't they take it off the shelf and take a fresh look at it here in March of 2002?

And sir, is there any -- you gave a partial

answer to that, and I want to give you a full opportunity, you were on kind of a short leash yesterday. Sir, is there any recent event or any particular event that you think might influence whether or not Schering today would pick up Niacor-SR off the shelf, if you will, and start marketing?

A. Recently -- well, Niacor-SR is, as you'll recall it, a competitor of Kos' Niaspan product. Niaspan has been selling and has been selling now successfully for some time. It still hasn't attained the level of sales that were expected for it back in 1997, and that sort of leaves us in a situation where even if Niacor were to be able to attain approval and the investments were made to bring it to market, the return on it would not be very great.

In fact, just recently there has been an announcement that a generic form of Niaspan is in the works, and a lawsuit has been filed by Kos against the generic manufacturer.

Q. Do you recall the party that has launched that litigation or launched an ANDA?

A. It's -- Kos launched the litigation against a company by the name of Barr Labs, who has filed for an ANDA, an abbreviated new drug application, which is the generic FDA approval.

Q. And when did that occur, sir?
A. The lawsuit was filed just the other day, recently. I saw it one day this week looking -- answering my internet channel -- news flashes.
Q. And is it a Hatch-Waxman setup where it's a generic to Niaspan?
A. Yes, yes. The Barr Labs is -- Barr Labs has announced that they want an ANDA, which would become a generic version -- the product of which would become a generic version of Niaspan.
Q. And how did this become public, do you know?
A. It was a press release from Kos. That was what I saw.
MR. GIDLEY: No further questions, Your Honor.
JUDGE CHAPPELL: Any further redirect from Schering?
MR. NIELDS: No, Your Honor.
MR. EISENSTAT: I just have a very few questions under my completeness doctrine objections, Your Honor, to finish getting into the record what I think is necessary to complete a few of the --
JUDGE CHAPPELL: Proceed.

RECROSS EXAMINATION

BY MR. EISENSTAT:
Q. Dr. Kerr, would you turn to tab 12 of your

redirect binder.

A. May I?

Q. Sure.

JUDGE CHAPPELL: Yes.

THE WITNESS: Yes, I have it. You said tab 12?

BY MR. EISENSTAT:

Q. Tab 12, yes, that's the -- as Mr. Gidley has admonished me a little bit, that's the correctly printed version of the Kos IPO document instead of the one I downloaded. This one has the right pages in it.

Do you have that in front of you?

A. Yes, I do.

Q. Will you turn to page 29 of the document bearing the Bates number AAA 0000080.

A. Did you say 80? I'm sorry.

Q. 80, yes, page 29.

A. Yes, I have it.

Q. Do you have that?

A. Yes, I do.

Q. Do you see the highlighted portion that Mr. Gidley directed you to, which reads, "Although most patients taking Niaspan will flush occasionally, the Company believes that the combination of Niaspan's formulation, its dosing regimen and proper dose titration should result in an incidence of flushing

episodes that are tolerable for most patients"?

Do you see that?

A. Yes, I do.

Q. Do you see how it continues then, "Niaspan's dosing regimen provides for the drug to be taken once-a-day at night; therefore, any flushing episodes will normally occur while the patient is sleeping. The Company believes that flushing during the night will not cause the discomfort or embarrassment that often accompanies the multiple daytime flushing episodes that occur with IR niacin."

Do you see that?

A. Yes, I do.

Q. And would anybody reading this section of the Kos IPO document, would they know that Niaspan was intended to be taken once a day at night?

A. Well, I -- "anybody" is too broad -- is too broad a population for me, but people reading it would tell you that the regimen provides for the drug to be taken once a day at night. I don't know that it needs to be or that it couldn't also be taken during the day.

Q. And let's go to tab 18 -- no, excuse me, I have the wrong tab number -- yes, tab 18, excuse me, tab 18. This is the document from Leonard S. Yaffe. Do you have that in front of you?

A. Yes, I do.

Q. Would you turn to the second page. There's a paragraph that begins, "Niaspan offers improved safety and side effects relative to niacin."

Do you see that section?

A. Yes.

Q. And if you go down about seven lines, there's a sentence that begins, "However."

Do you see that?

A. The second sentence begins, "However --"

Q. No, keep going, "However, in four-month studies --" do you see that?

A. Yes.

Q. It says, "However, in four-month studies compared to immediate release versions, Niaspan cut the monthly incidence of facial flushing by three-fourths to about two times per month. In addition, because Niaspan can be taken once daily before bed, most flushing incidents occur during the night, avoiding any embarrassment during the day. Liver toxicity occurred in less than one-tenth of 1 percent of the patients in all Kos' clinical trials, even lower than for HMG-CoA reductase inhibitor statins."

Do you see that section?

A. I do, yes.

Q. And if someone read this document, would they understand that niacin can be taken once daily at bed?

A. Yes, that's what it says.

MR. EISENSTAT: I have no further questions, Your Honor.

JUDGE CHAPPELL: Anything further?

MR. GIDLEY: No, Your Honor.

MR. NIELDS: No, Your Honor.

JUDGE CHAPPELL: Dr. Kerr, I have a couple questions. Volume 1, your direct exam exhibit binder, do you have that?

THE WITNESS: The Volume 1 of the direct? Yes, I do.

JUDGE CHAPPELL: Tab 8.

THE WITNESS: Tab 8.

JUDGE CHAPPELL: In your timing and probability analysis of the patent litigation, in your path analysis?

THE WITNESS: Yes.

JUDGE CHAPPELL: Over on the right side where you've got cases on appeal, 100 percent -- first, I have one question. I thought I heard you say that 100 percent probability of appeal by Upsher was a conservative estimate. How is 100 percent conservative?

THE WITNESS: Conservative in the sense that -- in the ultimate sense of what the timing is here. If we assumed that Upsher wouldn't appeal, if there was a chance that they wouldn't appeal, if instead of saying 100 percent we said let's say 50 percent, what would happen is that in some instances, some of the paths that we have to go through here, Schering would win at trial, instead of going to appeal, Schering wins, but if -- only if -- if Upsher only goes there 50 percent of the time to appeal, that means that there are instances where Schering would have gotten -- where Upsher would have been able to go to appeal, win an appeal, then go back to the trial court and win again. So, it removes some possibility of Upsher winning ultimately.

JUDGE CHAPPELL: Okay, I must have misunderstood you, because I took your testimony to be that, well, to be conservative, I will assume 100 percent chance that they would appeal.

THE WITNESS: Yes.

JUDGE CHAPPELL: And that's right?

THE WITNESS: Yes.

JUDGE CHAPPELL: Okay. And also on your analysis there on your tree, did you account for cases that were on appeal and while pending appeal, the

parties settled and dismissed by agreement?

THE WITNESS: I didn't explicitly. I'm just pausing, because I want to think about how that would work out as some alternatives. No, in each case, in each case we assumed or I assumed that the parties had 100 percent chance of appealing, which means that every trial court decision would go to the Federal Circuit.

JUDGE CHAPPELL: Okay, would --

THE WITNESS: For a final ruling by the Federal Circuit.

JUDGE CHAPPELL: And if they were pulled down by agreement, does that affect your analysis or your conclusion?

THE WITNESS: If during the period after the District Court decision, whatever that decision was, and the appeal -- the decision by the appeals court they settled the case -- it would really depend on how they settled it, Your Honor. I'm not -- I'm not certain about that. I mean, it would affect it. We would have to go back and do a number of different trees, but the nature of a settlement is what would determine how those trees -- branches work out.

JUDGE CHAPPELL: Okay, that's all I have.

Any follow-up questions based on my question?

MR. GIDLEY: I think one, Your Honor, if I may,

and it may turn into two.

FURTHER REDIRECT EXAMINATION

BY MR. GIDLEY:

Q. Dr. Kerr, let's go back to this point about whether 100 percent Upsher or Schering appeals is conservative, and I'll just set this up a bit. In your model, you assume that there's 100 percent chance of Schering appealing. Is that correct?

A. Yes.

Q. And you also assumed what percentage chance for appeal for Upsher?

A. 100 percent, yes.

Q. All right. Now, if Upsher-Smith was, for whatever reason, not willing to pursue an appeal from a loss, why is that conservative in terms of time, in terms of the ultimate outcome that you compute of February 2003?

A. Well, because that means that any time Schering -- if I were to take less than 100 percent certainty, if Schering -- if Upsher were not to appeal any outcome at the District Court level, that would move the time out to September of '96, because it essentially concedes the case at that point to Schering.

On the other hand, if Upsher takes its appeal,

it can go to the Federal Circuit, it can win at the Federal Circuit, and at that point either go to a new trial or be free of a patent restriction, and that would happen presumably earlier than September 2006.

So, by -- if we were to reduce the 100 percent, we would push the time out, because all -- any -- any time Upsher did not appeal, it automatically kicks out to the end of the period, which is the patent expiration in September of 2006.

MR. GIDLEY: I have no further questions, Your Honor.

MR. NIELDS: Your Honor, I apologize, and I hope I don't confuse the issue, but I think I now have questions following up on both of the Court's lines, if I may.

JUDGE CHAPPELL: Go ahead.

REDIRECT EXAMINATION

BY MR. NIELDS:

Q. Staying with this question of whether assuming 100 percent likelihood of appeal by both parties should they lose, and you're saying that that's conservative --

A. Yes.

Q. -- I just want to understand it. If you assume that both parties would appeal 50 percent of the time

or both parties would appeal 60 or both parties would appeal 70 or both parties would appeal 100, is 100 conservative as compared with both parties appealing 60 percent of the time?

A. No, it wouldn't be. I haven't done the arithmetic, but it would certainly not be.

Q. Okay. So, what you're saying is conservative is if you -- if you were to assume Schering would appeal 100 percent of the time that it loses and Upsher would only appeal 50 percent of the time it loses, then you would get a -- an expected date further out. Is that right?

A. Yes, that's right.

Q. And is your -- the reason you express it as conservative because you think that Upsher's shortage of cash might cause it to appeal less than 100 percent of the time? Is that what you're getting at?

MR. EISENSTAT: Objection, Your Honor, getting back to the issue of Upsher raising its cash poorness as a defense. I think we're just trying to get in the back door now areas that Upsher agreed not to get into before.

MR. NIELDS: I'm just trying to understand what he's saying, Your Honor. I felt it -- I had the same question that went in my head when he said conservative

as the Court did, and I'm trying to understand what he means by it.

JUDGE CHAPPELL: Well, the Upsher financial data is only admitted for a limited purpose, and that purpose will not expand based on this answer. So, your objection is sustained. I'm allowing the question, but that evidence has been admitted for limited purposes.

MR. NIELDS: Was there a pending question or did the witness answer it already?

THE WITNESS: I think I understood it, but --

JUDGE CHAPPELL: There's a question. Let's have Susanne read it back.

(The record was read as follows:)

"QUESTION: And is the reason you express it as conservative because you think that Upsher's shortage of cash might cause it to appeal less than 100 percent of the time? Is that what you're getting at?"

JUDGE CHAPPELL: Go ahead.

THE WITNESS: That's one reason, and actually there are a number of reasons. There are many reasons why Upsher might not have -- might not have appealed. Shortage of cash is one. The appeal is going to be expensive. It's going to increase their legal fees substantially.

Also, I've talked before about Upsher being a

small company and the people who would no doubt be involved in the appeal. An appeal that can drag on for more than a year means that people like Dr. Robbins and Mr. Troup and perhaps the others would be tied up and wouldn't be able to do their jobs, and there's a number of different reasons, and not to mention the fact that an appeal is time-consuming, and knowing that the appeal can drag on, that just reduces the value to them of winning the litigation.

BY MR. NIELDS:

Q. Just so we understand, if we assume that both parties would appeal the same percentage, whatever that percentage is, then your assumption of 100 percent isn't even conservative or whatever the opposite is?

A. Yes, it should work out to be similar.

Q. Now, going to the Court's second area of questioning, which is what would -- how the fact that parties might settle while the appeal is pending, how that affects your data, here's my question that I don't understand:

If that occurred in some number of cases that's in your data set, i.e., there was an appeal, it -- the parties settled before the Court of Appeals rendered a decision, how would that appear in your data? Would that case fall out of the number of cases that you

considered or would it appear as -- as something that would affect your data in some way that we didn't know about before?

A. No, it would -- the data is based on cases that have been appealed and have been decided by the Federal Circuit. So, the data for the length of time, the 19 months, does not reflect cases that settled prior to appeal.

I do know, though, and from working with the database, that in patent law, it's very, very common -- it's uncommon for cases to be left without appeal. So, the 100 percent in that sense is not -- is not terribly conservative. Most patent cases end up being appealed to the Federal Circuit.

Q. Right, but I'm not asking you about the hundred percent anymore.

A. No, I understand.

Q. I'm asking you about if you had, for example, 200 cases in your data set where appeals were filed and five of them got settled on appeal, would that mean that your statistics were generated out of the other 195?

A. The statistic deals with the 19 months, yes.

Q. Okay.

A. Yes. And the proportion is about right.

MR. NIELDS: I have nothing further, Your Honor.

JUDGE CHAPPELL: Anything else?

MR. EISENSTAT: I have no more questions, Your Honor.

MR. GIDLEY: No, Your Honor.

JUDGE CHAPPELL: Thank you, Dr. Kerr. You're excused.

THE WITNESS: Thanks.

JUDGE CHAPPELL: Next witness?

MR. NIELDS: Your Honor, our next witness is Peter Safir. He is an FDA law expert responding to complaint counsel's expert Joel Hoffman, and we have once again -- if the Court approves it, we have worked out a written direct, which complaint counsel has seen and agreed to or had no objection to, and we will do no more than a 15-minute oral direct in court, and then we will go straight to cross examination.

JUDGE CHAPPELL: That's fine with me. As long as your previously prepared direct is an exhibit that's not objected to and admitted into evidence, then it's received for all purposes.

MR. NIELDS: Thank you, Your Honor, and Mr. Charles Loughlin will be questioning Mr. Safir for Schering.

JUDGE CHAPPELL: Okay.

Raise your right hand, please.

Whereupon--

PETER O. SAFIR

a witness, called for examination, having been first duly sworn, was examined and testified as follows:

JUDGE CHAPPELL: Thank you, have a seat.

State your full name for the record, please.

THE WITNESS: Peter Safir.

DIRECT EXAMINATION

BY MR. LOUGHLIN:

Q. Mr. Safir, what is your profession?

A. I'm an attorney specializing in the practice of Food and Drug law.

Q. And where are you employed?

A. I'm a partner at the law firm of Kleinfeld, Kaplan & Becker.

Q. And how --

A. Here in Washington.

Q. And how long have you been practicing in the area of Food and Drug law?

A. Approximately 27 years.

Q. And in the course of your practice, do you advise clients with respect to issues related to the 180-day exclusivity provisions of the Hatch-Waxman Act?

A. Yes, I advise clients in connection with all aspects of the Hatch-Waxman Act, including various exclusivities, including the 180-day exclusivity provisions.

Q. And Mr. Safir, do you also teach in the area of Food and Drug law?

A. Yes, I'm a professorial lecturer of Food and Drug law at the George Washington University Law School. I teach a Food and Drug law course every spring.

Q. And how long have you been doing that?

A. I have had that appointment since 1991.

Q. Have you published any articles in the area of Food and Drug law?

A. Yes, I've published a number of articles and given many, many speeches.

Q. And do any of those articles relate to the Hatch-Waxman Act?

A. Yes, at least two of the law journal articles are directly on the Hatch-Waxman provisions.

MR. LOUGHLIN: Your Honor, at this time Schering offers Mr. Peter Safir as an expert in FDA regulatory law.

MR. NARROW: We have no objection, Your Honor.

MR. CURRAN: No objection, Your Honor.

JUDGE CHAPPELL: Motion is granted.

BY MR. LOUGHLIN:

Q. Mr. Safir, are you prepared to offer your opinions in this matter today on certain issues related to 180-day exclusivity?

A. Yes, I am.

Q. And have you written a statement setting forth those opinions?

A. Yes, I have.

MR. LOUGHLIN: Your Honor, may I approach the witness?

JUDGE CHAPPELL: Yes, you may.

BY MR. LOUGHLIN:

Q. Mr. Safir, I've handed you what's been marked as SPX 1277. Is that the written statement you just referenced?

A. Yes, it is.

Q. And are you adopting SPX 1277 as your testimony in this matter?

A. Yes, I am.

MR. LOUGHLIN: Your Honor, at this time I move for the admission of SPX 1277.

MR. NARROW: No objection, Your Honor.

MR. CURRAN: Your Honor, I haven't had a chance to review this. May we defer the admission of this --

I don't want to hold anything up, but may we defer the admission of this until the next break?

JUDGE CHAPPELL: Yes, I'll allow you to re-offer it, Mr. Loughlin, at that time.

MR. CURRAN: Thank you, Your Honor.

MR. LOUGHLIN: Thank you, Your Honor.

JUDGE CHAPPELL: Any objection to the witness discussing this information before it's admitted?

MR. CURRAN: Not at all, Your Honor.

JUDGE CHAPPELL: Thank you.

You may proceed.

BY MR. LOUGHLIN:

Q. Mr. Safir, what was the scope of your assignment in this matter?

A. I was asked by counsel for Schering-Plough to provide an expert opinion in connection with this case, and specifically I was asked to provide my opinion on four questions regarding the application of 180-day exclusivity rule.

Q. And are those questions set forth in your written statement, SPX 1277?

A. Yes, they are set forth in paragraph 3 on page 2.

Q. Now, are you familiar with Mr. Joel Hoffman?

A. Yes, I am.

Q. And who is he?

A. Mr. Hoffman is a lawyer practicing in the area of Food and Drug law here in Washington, and I believe he was an expert witness for the FTC in this matter.

Q. And have you read the trial testimony that Mr. Hoffman gave in this matter on February 6th of this year?

A. Yes, I have.

Q. And do you agree with his testimony?

A. I agree with parts of it, and I disagreed with some parts of it.

Q. Now, did you read Mr. Hoffman's testimony regarding the factual background related to the 180-day exclusivity in this case?

A. Yes, I did.

Q. And did you agree with his testimony in that regard?

A. Yes, I'm in substantial agreement with his summary of the history.

Q. Okay. Now, Mr. Hoffman was asked to opine on four questions by complaint counsel. Are you aware of that?

A. Yes, I am.

Q. Do you agree with Mr. Hoffman's opinion on the first question he was asked, which was whether or not

on June 17th, 1997 there was substantial uncertainty as to Upsher's eligibility for 180-day exclusivity if it settled its lawsuit with Schering?

A. Yes, I agree with that -- with that opinion. I'm familiar with it, and I agree with it.

Q. You agree with his testimony that there was substantial uncertainty?

A. Yes, there was substantial uncertainty.

Q. Do you agree with Mr. Hoffman's opinion with respect to the second question asked by complaint counsel, which was whether on January 23rd, 1998 there was substantial uncertainty as to Upsher's eligibility for exclusivity given that it had settled with Schering?

A. Yes, I also agree with that, and in my view, there was probably more uncertainty on that date. I pretty much agree with what Mr. Hoffman said.

Q. Now, do you agree with Mr. Hoffman's opinion with respect to the third question he was asked, which was whether between June 1998 and February 28th, 2002 Upsher-Smith was eligible for 180-day exclusivity?

A. I have some disagreement with Mr. Hoffman on that -- on that question.

Q. And what is your disagreement?

A. I believe that during that time, had another

applicant challenged Upsher's exclusivity, that there is a likelihood that FDA would have determined, as it did in the Teva citizen petition situation, which I believe Joel Hoffman described, that Upsher was -- although it had received exclusivity upon approval of its application -- would no longer have been eligible for exclusivity.

Q. Okay. Now, are you aware of Mr. Hoffman's opinion that under current law, if a first ANDA filer litigates with the patent holder and loses that lawsuit, the ANDA filer is nonetheless entitled to 180-day exclusivity?

A. Yes, I read his -- his statements to that effect in the transcript.

Q. And do you agree with his opinion in that regard?

A. No, I disagree with his opinion.

Q. And why is that?

A. I believe that certainly at least since '99, 1999, following the Mova Court of Appeals decisions, Mova and Granutec decision, FDA has taken the position that a first filer who litigates and loses, according to an FDA regulation, must change its certification from a Paragraph IV to a Paragraph III, and therefore is no longer viewed as a Paragraph IV filer, and since

only Paragraph IV filers are eligible for 180-day exclusivity, such a first filer that loses would not be entitled to exclusivity.

Q. Now, is FDA's view of exclusivity in the case of an ANDA filer that litigates and loses relevant to your opinion of whether an ANDA filer gets exclusivity after settling?

A. Yes, it is. My opinion on that issue is largely based on FDA's actions in the Teva/Mylan situation, where Teva had filed a citizen petition objecting to Mylan receiving exclusivity after it had settled litigation, and FDA in its response to the citizen petition said that Mylan, by taking a license to market the product in the future, was no longer litigating the matter, was, in effect, conceding the validity and infringing nature of -- or that it was infringing the patent and was therefore in a similar situation to a litigant that lost, and therefore, had to change its certification from a IV to a III or, in effect, de facto change its certification from a IV to a III and was no longer entitled to exclusivity.

Based on that, it was my view that FDA would take the position that another settler that also took a future license and was no longer contesting the patent could also lose its exclusivity.

Q. Now, has FDA's position in that regard been challenged?

A. Yes, it has.

Q. And what was the result of that challenge?

A. Mylan appealed FDA's decision to the District Court in West Virginia, and the Court disagreed with FDA and reversed FDA's action. That case was then appealed by FDA and Mylan in another matter, another part of it, and ultimately the case was dismissed by Mylan, but FDA took a very strong position in its brief that it was correct and that the District Court was wrong.

Q. And is FDA's current position the same one that it explained or proffered in its appeal of the Mylan case?

A. I have no reason to believe they've changed their position. They -- it was stated in their brief, and the issue really hasn't come up since. So, I have no reason to believe they've changed their position.

Q. Now, how does FDA's position taken in the Teva citizen petition and the Mylan appeal affect your view of Upsher's eligibility in this case for exclusivity?

A. Well, Upsher received exclusivity when it was -- when it got its approval. So, we're talking hypothetically here, because it was never challenged,

and I -- for example, in the Teva litigation, I'm not sure that if Teva ever challenged Mylan, FDA would have made -- would have done anything, but had another ANDA applicant gone to FDA, such as Teva did, within the same time frame, I think the facts are very analogous.

You have a license, you have a future marketing. At the time someone would have gone to FDA, the ANDA product was not being marketed, and there was a license taken indicating that there was, in effect, a view that the patent was valid and infringed, so I think FDA would have ruled the same way.

Q. Now, Mr. Safir, when was the Teva citizen petition filed?

A. I believe that was filed -- I'm not sure of the date. I believe it was filed maybe in 2000.

Q. Was it February of 2001?

A. Let's see, the petition -- I'm just not sure of the date. I know the decision I think was in March of 2001, because the -- the Mylan case was decided in 2001. So, I'm not sure when it was filed.

Q. Do you recall when the Mylan appeal brief by the FDA was --

A. Yes, I think that was in May-June 2001.

Q. Okay. Now, you mentioned the likelihood of a -- or the possibility of a challenge by another ANDA

filer. Do you know if anyone did challenge Upsher's eligibility for exclusivity?

A. To my knowledge, no one, no one ever challenged it.

Q. Okay. Now, Mr. Safir, with regard to the fourth question that Mr. Hoffman was asked by complaint counsel, do you agree with Mr. Hoffman's opinion on that question, which was -- the question was whether or not on June 17th, 1997 and January 23rd, 1998 there was a substantial possibility that a court decision in the Schering-ESI litigation would trigger any exclusivity to which Upsher may have been entitled.

A. I have a difference of degree with Mr. Hoffman on that. First of all, on June 17th, I think there was relatively little possibility. At that point, Granutec -- FDA had not announced its publicly its decision in Granutec, which was the first time they actually talked about a party other than the first filer or a decision in a case other than that involving a first filer to trigger the first filer's exclusivity.

By January of '98, FDA had made that decision. That -- FDA's decision had been overturned by the Granutec court. The case was on appeal. Certainly there was a possibility, because FDA had -- had ruled that way, but in my view, it was no more than a 50/50

likelihood at best that that -- that that could happen.

Q. All right. Now, Mr. Safir, do you have an opinion on the issue of whether a first ANDA filer's rights to 180-day exclusivity may be waived or transferred to a third party for consideration?

A. Yes, I do.

Q. And what is that opinion?

A. I believe that the 180-day exclusivity rights can be waived in favor of one or more of the parties, either for consideration or not, and that they could be transferred as well.

Q. And what is the basis for your opinion?

A. With respect to the waiver, I think it's very clear. I mean, FDA in its lead proposed rules in '95 talked about waivers. In the Granutec case itself, that is what happened. Genpharm received exclusivity but could not go to market because it hadn't been approved, so it, in exchange for a payment, waived it with respect to Granutec. There was a lawsuit brought by another ANDA holder, Boehringer Ingleheim, and the Court upheld the fact that the waiver was allowed. It was again mentioned at the -- at the Court of Appeals. So, I don't think there's any question there.

With regard to a transfer, that hasn't been mentioned specifically in any FDA document. In my

view, it is -- once the 180 days has been granted, it goes along -- it's one of the rights of the ANDA applicant, and if that ANDA were sold or if the applicant were merged or if something happened to transfer that NDA, the -- the 180 days would go along with it.

MR. LOUGHLIN: Okay, thank you, Mr. Safir.

I have no further questions, Your Honor.

JUDGE CHAPPELL: Any further direct?

MR. CURRAN: Nothing for Upsher, Your Honor.

JUDGE CHAPPELL: Cross?

MR. NARROW: Thank you, Your Honor.

JUDGE CHAPPELL: Is this our last witness or is there another witness?

MR. NIELDS: This is our last witness for today, Your Honor.

JUDGE CHAPPELL: Then I don't anticipate another break, Mr. Curran, just so you -- if you need to review that document now.

MR. CURRAN: Okay, I was doing a lot of that while the witness was testifying, Your Honor. I'll continue to do that and should have an answer before cross is done.

JUDGE CHAPPELL: Thank you.

CROSS EXAMINATION

BY MR. NARROW:

Q. Good afternoon, Mr. Safir.

A. Good afternoon.

Q. I'm David Narrow. You may recall that we met before. I was the FTC attorney who took your deposition last November.

A. Yes.

Q. Now, you prepared your written direct expert testimony for today. Is that correct?

A. Yes, I did.

Q. And that testimony has been identified as SPX 1277. Is that correct?

A. Yes, it has.

Q. And to the best of your knowledge and belief, your written testimony in SPX 1277 is accurate and truthful, isn't it?

A. Yes, it is.

Q. Okay. You checked it over, didn't you?

A. Yes.

Q. Okay. And when did you prepare SPX 1277?

A. I prepared it sometime in the last few weeks after I was told that that's the way it was going to be presented.

Q. Okay. And your testimony was proffered under oath, just as though you had presented that full

testimony live in court today. Is that correct?

A. I believe that's so, yes.

Q. You signed it at page 16, didn't you, under oath?

A. Yes.

MR. NARROW: Your Honor, may I approach with some documents?

JUDGE CHAPPELL: With all that? Yes, you may.

MR. NARROW: With luck, I won't need to use all of it, Your Honor.

JUDGE CHAPPELL: I need to also remind the attorneys to take back your binders at the end of the day. We're building a barricade here.

BY MR. NARROW:

Q. Now, Mr. Safir, you also prepared an expert report in this matter earlier, didn't you?

A. Yes, I did.

Q. Okay. And your expert report is identified as SPX 663 in the binder, isn't it?

A. Yes, it is.

Q. Okay. That's the expert report that you prepared in this matter, correct?

A. Yes, it is.

Q. And that was prepared on or about October 8th, 2001. Is that correct?

A. Yes, that's right.

Q. Okay. In both your expert report and your written testimony that you proffered today, SPX 1277, in many places cite your support for statements that precede the citations in your report and your testimony. Is that correct?

A. I'm sorry?

Q. There are citations of --

A. Yes.

Q. -- support for statements that are in both your report and your expert testimony. Is that right?

A. Yes.

Q. Now, as an attorney, you would agree with me that the purpose of expert testimony is to provide the Court with reliable information and opinions by qualified individuals in order to help the Court reach an informed decision in whatever matter is before the Court?

A. Yes.

Q. And unreliable expert opinions aren't helpful to the Court in reaching an informed decision, are they?

A. That's probably true, yes.

Q. And part of assuring that an expert's opinion was reliable involves consideration of the information

supporting the expert opinion. Isn't that correct?

A. Yes.

Q. So, if the claimed support for an expert opinion does not, in fact, support that opinion, then the opinion isn't reliable. Is that correct?

A. If the support is not there, it would not be reliable.

Q. So, for example, if an expert witness based his or her expert opinion on an assertion that a court decision explicitly said something and the court decision, in fact, didn't say that, you would agree that an opinion relying on that would be not reliable. Isn't that correct?

A. I would think that would be true if that were -- yes, if there were no opportunity, for example, as we might have now with an oral discussion to correct it.

Q. Okay. Now, let's turn to SPX 1277, your written direct testimony that was presented today, okay?

A. Um-hum.

Q. And let's turn to paragraph 23 at the bottom of page 12, please.

A. Yes.

Q. And let's also turn to paragraph 23 on page 14

of your expert report.

A. Um-hum.

Q. Now, on paragraph 23 of your expert testimony, in the first sentence, you offer the word-for-word identical opinion as you did in the first sentence of paragraph 23 of your expert report.

A. I'm sorry, I'm -- tell me --

Q. I want you to compare paragraph 23 of your testimony with paragraph 23 of your expert report.

A. Right, okay.

Q. And the first sentence of those paragraph 23s are identical, aren't they?

A. Yes, the first sentence.

Q. Okay. And the only source that you cite as support for that first sentence in both paragraph 23s are the same remarks by Commissioner Leary. Is that correct?

A. No, that's the -- well, yes, that's the only source I cited as a "see," as examples, yes.

Q. You have the same first sentence and the same citation as support for that first sentence. Is that correct?

A. Right, yes.

Q. Okay. Now, would you turn to CX 614 in your binder, please.

A. Um-hum.
Q. Do you recognize CX 614?
A. Yes.
Q. And what is that?
A. That's the remarks of Thomas B. Leary on November 3, 2000.
Q. Okay. And is CX 614 the remarks of Commissioner Leary that you cite for support for the first sentence of paragraph 23 in both your direct testimony and your written expert report?
A. Yes. Yes, it is.
Q. Okay. Now, please turn to page 2 of CX 614.
A. Um-hum.
Q. Actually, before you do that, would you please read the first sentence of paragraph 23 of your expert testimony?
A. "The FTC has indicated that a prohibition against waiver or transfer of exclusivity in patent settlement agreements between pioneer and generic companies is potentially anti-competitive."
Q. Okay. Now, turning to the top of page 2 of CX 614, would you please read the first full sentence on the top of page 2?
A. "I also speak for myself and no other Commissioner."

Am I reading the right thing?

Q. I think you left out the word "only." Would you try that again, please?

A. "I also speak only for myself and no other Commissioner."

Q. So, regardless of the Federal Trade Commission's position or policy on any issue, these remarks by Commissioner Leary are not a statement of the Federal Trade Commission's position or policy, are they?

A. No, I would disagree with that. The reason I disagree with that is if you look in this article, he cites the consent order -- this is on page -- and it's not numbered -- this is -- it looks like page 9, the very top, it looks like page 9 of -- I don't know, 13, and he cites a consent order entered in the Abbott-Geneva case, and in this talk -- this is -- this is the Commission order, and it says, "Outright prohibitions of agreements that, B --" I'm sorry, "that, A, restrict the generic company's ability to waive its Hatch-Waxman exclusivity rights," and he's talking about that is in the order, and indeed, when I went back -- and I've looked at that order.

That order has a specific language in it that bars Abbott and Geneva from either restricting any

waiver or transfer of rights. So, I cited this as, you know, an example. He was -- he may have been speaking for himself, but he was quoting from the Commission's order. So -- but I would agree with you, he was speaking for himself.

Q. Okay. So, Commissioner Leary was not speaking for the Commission; he was speaking for himself in these remarks.

A. That's right, absolutely.

Q. So, while the Abbott and Geneva consent order might support your position, Commissioner Leary's remarks don't support it.

A. Well, to the extent he quotes from the consent order, I mean, he is -- he may be speaking for himself, but he -- I mean, if that's an order, he must have -- the order was signed by the Commission, but I'm not going to disagree that he stated that he's speaking only for himself. I'm citing this document as support for the statement that I made in here.

Q. Now, Commissioner Leary's remarks, while addressing waivers of exclusivity, don't mention transfers of exclusivity, do they?

A. No, his -- he -- his statement does not mention transfer; however, the order does.

Q. Do the parts that are cited by Commissioner

Leary in his speech mention transfer?

A. No, he cites the order. He is -- he does not mention transfer in here.

Q. Okay. Now, the FDA has the responsibility to implement the Hatch-Waxman Act, doesn't it?

A. Yes, it does.

Q. Okay. And at various times, the FDA has interpreted various provisions of the Hatch-Waxman Act in order to implement it. Is that correct?

A. Yes.

Q. And sometimes the FDA has adopted formal regulations interpreting various provisions of the Act, correct?

A. Correct.

Q. And sometimes the FDA has issued guidance documents of various types as to how it will interpret certain provisions of the Hatch-Waxman Act.

A. Yes, it has.

Q. And sometimes the FDA has attempted to implement its interpretation of certain provisions of the Hatch-Waxman Act through specific decisions. Isn't that correct?

A. Yes.

Q. And an example of that would be the June 1997 letter to Genpharm and the other ranitidine ANDA filers

where the FDA indicated that a court decision in a later patent infringement suit not involving the first filer might trigger a first filer's exclusivity. Isn't that correct?

A. I believe that came out in a letter. I don't know if you have a cite -- if you have a copy of the letter -- I know it came out in a letter, that FDA made a statement to that effect, yes.

Q. Okay. And sometimes the FDA attempts to implement its interpretations of certain provisions of the Hatch-Waxman Act through its responsible citizen's petition, correct?

A. Absolutely, yes.

Q. And that was what occurred with the Teva citizen's petition?

A. Right.

Q. Okay. And in the Teva petition, that policy was that the -- adopted by the FDA was that under certain circumstances that were present in that situation, that was the subject of the Teva petition, the FDA could imply that a first Paragraph IV certifying ANDA filer had effectively changed its certification from a Paragraph IV to a Paragraph III. Is that correct?

A. That's the gist of what its response was to --

to Teva.

Q. And that that implied change to a Paragraph III could result and would result in that instance in the revocation, if you will, of the first Paragraph IV ANDA filer's entitlement to 180-day exclusivity.

A. Yes, that's essentially what they ruled in that case.

Q. But the FDA isn't the final arbiter of its interpretations of the Hatch-Waxman Act, is it?

A. Well, it's the final arbiter of its interpretation. It may not ultimately -- I mean, they can be challenged in court.

Q. Right, and the FDA's actions and decisions are all subject to challenge in Federal Court. Isn't that correct?

A. Yes.

Q. And in point of fact, a substantial number of FDA interpretations of the Hatch-Waxman Act have been challenged in court. Isn't that correct?

A. Yes.

Q. And sometimes the FDA's interpretation and position has been overruled or overturned by the Federal Courts, correct?

A. Yes, that's correct.

Q. Now, any plaintiff that has standing to sue the

FDA can do so in the Federal District Court for the District of Columbia. Is that correct?

A. That's correct.

Q. Okay. And that's because the Federal District for the District of Columbia is the official headquarters of the FDA. Isn't that right?

A. I believe it is. They certainly can be sued by anyone in the Federal District Court of the District of Columbia.

Q. So, a decision by the Federal District Court for the District of Columbia potentially is something that the FDA has reason to pay particular attention to, isn't it?

A. Yes.

Q. Because most any other plaintiff could sue the FDA in that court and presumably get the same result.

A. That's -- that's correct.

Q. And one would expect, wouldn't one, that for the same reason, any entities that deal with the FDA and are affected by its decisions, such as pharmaceutical manufacturers, also would pay particular attention to any decision of the Federal District Court for the District of Columbia?

A. Well, it -- I mean, it depends. I mean, there are a number of cases decided in the District Court

relating to FDA that are so specific that people other than the parties wouldn't pay much attention to them, but if it relates to a broad issue, there's -- there's no question that people will pay attention, obviously subject to the right to appeal it to the D.C. Circuit.

Q. Sure, but those entities that deal with the FDA would know or have some reason to believe that they could get the same or a similar result if they sued the FDA in D.C. Federal Court.

A. I think that's correct, yes.

Q. Okay. Now, page 4 of your direct testimony at the end of paragraph 9, you state that, "Therefore, on June 17th it was reasonable, even prudent, to believe that Upsher would not be entitled to exclusivity, unless it successfully defended the patent suit brought by Schering."

Is that correct, that's what you say?

A. Yes.

Q. Now, you're not saying that it was clear on June 17th that Upsher-Smith had to, in fact, successfully defend its patent infringement suit in order to be entitled to exclusivity, are you?

A. I don't think that's what I've said. I think I said what you read, that it was reasonable and even prudent to believe that Upsher would not be entitled to

exclusivity unless it successfully defended.

Q. But your implication was not that it was necessary, in fact, that it was clear that Upsher would have to successfully defend to be entitled to exclusivity. Is that correct?

A. I believe I said what I said. I think that what I'm saying here and in my testimony is that there was -- there was uncertainty.

Q. Okay. Now, in January of 1997, the Federal District Court for the District of Columbia in the Mova case had enjoined the FDA approval of Mylan's ANDA for micronized glyburide until after the trigger and running of Mova's 180-day exclusivity despite Mova's not having successfully defended in its patent infringement litigation. Is that correct?

A. That's essentially correct, yes.

Q. Now, the Mova District Court's reasoning was that the Hatch-Waxman Act was clear on its face as to what was required to be eligible for 180-day exclusivity. Isn't that correct?

A. I think that was the -- yes, the Mova court -- District Court said that, yes.

Q. And the court stated that the statute contained no requirement that a first Paragraph IV ANDA filer successfully defend any patent infringement litigation

in order to be entitled to 180-day exclusivity. Is that correct?

A. I believe that's correct.

Q. And the court said that the statute contained no requirement that there even be any patent infringement litigation for a first Paragraph IV ANDA filer to be entitled to 180-day exclusivity. Isn't that correct?

A. Yes, that's right, a previous court actually had also said that.

Q. And the District Court said that it was Mova's being the first to file an ANDA with a Paragraph IV certification that alone entitled Mova to 180-day exclusivity. Isn't that correct?

A. Yes, the District Court's decision was pretty broad to that effect, yes.

Q. Okay. And the District Court enjoined the FDA from approving any subsequent ANDAs for the product at issue until Mova's exclusivity had been triggered and run.

A. Right, for that -- for that specific product, that's right.

Q. Right. Now, in explaining its decision, the Mova District Court cited a 1989 decision, the Inwood Laboratories, Incorporated vs. Young decision. Isn't

that correct?

A. Correct.

Q. And that was also rendered by the Federal District Court in the District of Columbia, correct?

A. That's correct.

Q. Now, the issue in Inwood was that the FDA was trying to approve ANDAs other than the first Paragraph IV certifying ANDA filer based on its interpretation in that case that the company, Inwood, which was the first Paragraph IV ANDA filer, was not entitled to 180-day exclusivity because it hadn't been sued for patent infringement. Isn't that right?

A. Yes.

Q. And the District Court in the Inwood case enjoined FDA from approving any subsequent ANDAs for the drug in question until after the running of Inwood's 180-day exclusivity period. Isn't that correct?

A. That's right.

Q. And in Inwood, the reason that the District Court gave was that the Hatch-Waxman Act's requirement for eligibility for 180-day exclusivity was clear in the statute, okay, and that these did not include a requirement of -- that the first Paragraph IV certifying ANDA filer be sued for patent infringement.

Isn't that correct?

A. I believe that's the gist of it. I don't recall the specifics of that case. I mean, I know the case, but I don't know the -- each specific holding.

Q. Are you saying that you do recall that that was the reasoning of the Court?

A. I recall the outcome and the general basis of the case. I -- without having the case in front of me, I would not want to, you know, say I remember every --

Q. Well, why don't you take a look at CX 1714, which is in your binder, and if you will turn to page 1526, the top right. And at the top right it says, "There is no ambiguity that requires the Court or permits the FDA to read into it," being the statute, "a requirement of a lawsuit which is simply not there."

A. Right.

Q. Okay. And -- okay, so it's -- the Inwood reasoning simply was that the statute was clear on its face as to what was required --

A. Yes, that was --

Q. -- and the FDA wasn't entitled to add an additional requirement.

A. That's right.

Q. In that case, being sued. Is that correct?

A. That's correct.

Q. Okay. And in the Inwood decision, the District Court also said that even if application of the statute as drafted in some cases led to outcomes at odds with purposes of the statute, even by delaying the generic entry to the market, this didn't permit the FDA to add a new requirement to 180-day exclusivity. Is that correct?

A. That's correct.

Q. Now, the Mova court's citation to the Inwood decision stated that the Inwood decision had been vacated as moot in 1989, didn't it?

A. Yes.

Q. But the Mova District Court in 1997 still cited Inwood as support for its reasoning in deciding the Mova case, didn't it?

A. The Mova District Court I believe cited it.

Q. So, the Mova District Court apparently believed that the reasoning for the 1989 Inwood opinion was valid and applicable in 1997, didn't it?

A. Presumably by citing it they did, yes.

Q. All right. Even though the Inwood decision had been vacated?

A. Had been vacated, yes.

Q. Okay. And again, the reasoning of the court in Inwood, which was also the reasoning of the court --

the District Court in Mova, was that the Hatch-Waxman Act was clear on its face as to what was required for 180-day exclusivity. Isn't that correct?

A. Well, it wasn't the same case, but in both cases, they said it was clear, yes.

Q. The reasoning was that the statute was clear on its face.

A. Yes.

Q. In both cases.

A. Yes, the statute was clear -- the court said that in each case, that's right.

Q. Right, and the court said in both cases, though they were dealing with different facts, that the FDA was not free to add an additional requirement to what was clear in the statute. Is that correct?

A. Yes.

Q. Okay. And what the statute says was required for -- to be eligible for 180-day exclusivity was that an ANDA filer be the first Paragraph IV certifying the ANDA filer. Is that correct?

A. That's the way they -- that's the way they interpreted -- basically based on the fact that the triggers that were written into the statute, that neither one seemed to require a lawsuit, that's right.

Q. The courts in both Mova and in the Inwood

District Court said that to be eligible for 180-day exclusivity, the statute says you must be the first ANDA filer with a Paragraph IV certification, correct?

A. That's correct.

Q. And that's it.

A. That's certainly what the court in Mova said. In Inwood, I think they said certainly you did not have to be sued.

Q. In Inwood -- in Inwood, again, turning to the same point, under Roman numeral IV, "The statute is clear on its face." Is that correct?

A. Yes, they said that.

Q. Okay. And the court in Inwood did not identify any other requirement other than being the first Paragraph IV ANDA filer, is that correct, in order to be entitled to 180-day exclusivity?

A. No, I don't believe it did, no.

Q. So, Inwood held that in the case before it, the FDA couldn't add a requirement for exclusivity that the first Paragraph IV ANDA filer be sued for patent infringement, right?

A. That's correct.

Q. And in Mova, the District Court held that in the case before the court, the FDA couldn't enter a requirement for exclusivity that the first Paragraph IV

ANDA filer successfully defend a patent infringement litigation. Is that correct?

A. That's correct.

Q. Okay. So, even before the Mova District Court decision in 1989, the date of the Inwood decision, the FDA and the pharmaceutical industry had some indication that the District Court for the District of Columbia was not receptive to the FDA adding requirements for 180-day exclusivity beyond that which was clearly stated in the Act. Isn't that clear?

A. Well, people were aware of the Inwood case, certainly we were, that was my firm that argued that case, so we knew that case, but it had been vacated as moot, and subsequent to that point, when FDA published its regulations on the Hatch-Waxman Act, I believe in '89, they specifically discussed the Inwood case and said they disagreed with it and were not going to -- they were not going to follow it, particularly since it had been vacated. They were very insistent, in fact, on vacating that case. So, people clearly knew about it.

The arguments were there, so that the arguments that were brought up in Mova and the reasoning that ultimately decided Mova was not something that was -- that was brand new, but I would certainly not say that

between 1989 and 1998, when that was -- when Mova was decided, that the industry was thinking that the successful defense was something that, you know, wasn't -- I mean, the regulation had been passed, the regulation hadn't been challenged, and that was the way people were operating.

So, yes, there was an earlier case. Yes, it had been vacated. And yes, the Mova court resurrected the reasoning in that case, but in the interim, clearly the industry did not believe that the successful defense requirement was something that was not going to be upheld.

Q. The reasoning in Inwood wasn't vacated, was it?

A. Well, when a case is vacated, I mean, you can't vacate the reasoning. It's there.

Q. Obviously. Mova, in fact, cited Inwood.

A. Yes.

Q. Okay. And the Court of Appeals for the D.C. Circuit subsequently affirmed the Mova District Court decision, didn't it?

A. Yes, but not quite the same way. It basically said that FDA's regulation was overly broad and that -- clearly left the door open that FDA could adopt a new regulation that could deal with some of the issues in Mova. It's just that it was -- it was overly broad.

So, the D.C. Circuit's decision in Mova was certainly less sweeping than the District Court's decision and much more reasoned actually.

Q. Would you please turn to CX 1721, which is the Court of Appeals decision in Mova?

A. Um-hum.

Q. Turn to page 1068, please. In the highlighted part, the Court of Appeals says, "Here, the FDA cannot point to any particular ambiguity in the words of Section 355(j)(5)(B)(iv) that permits it to interpolate its 'successful defense' requirement."

Is that what the opinion says?

A. Yes.

Q. And what is section 355(j)(5)(B)(iv)?

A. Well, that's the 180-day provision.

Q. You're certainly not saying that between 1989 and the Mova decision in January of 1997 there was certainty about -- that there was certainty that FDA could impose additional requirements beyond those that were in the statute, are you?

A. No, what I'm saying is that FDA subsequent to the Inwood decision proposed and passed final regulations that codified the successful defense requirement. Those remained in effect and were operated under by FDA and industry up to the time of

the Mova case.

Q. Right. So, FDA adopted a position, but those were --

A. Well, they adopted regulations.

Q. Right, and those were challenged and held to be unlawful.

A. The -- they were challenged in 19 -- yeah, '87 -- I'm sorry, in 1997, but -- and regulation is always subject to challenge.

Q. Right, and, in fact, that additional requirement for exclusivity was overturned by the Mova District Court.

A. As expressed in those regulations.

Q. Right, and that was affirmed by the Court of Appeals.

A. Yes.

Q. Now, in May of 1997, an FDA representative announced at a public meeting that FDA was going to acquiesce in the Mova District Court decision at least temporarily pending appeal of the Mova District Court decision. Is that correct?

A. That's correct.

Q. And by acquiescing in the Mova District Court decision pending appeal, the FDA meant that while the Mova decision was on appeal and until it was reversed,

the FDA intended not to apply the successful defense requirement to a first Paragraph IV ANDA filer in order to be entitled to 180-day exclusivity. Isn't that correct?

A. I -- not on -- on May 21st, when that was announced, I don't think that was clear at all. It became clear after -- around June 18th or 19th when the FDA's response to Granutec, Genpharm, Lipha in the context of ranitidine came out. At the time of the statement, which was at a Food and Drug Law Institute conference, I believe, the statement was fairly short. It said we are -- we think that decision is flat wrong. We've appealed. We're going to acquiesce, but if you guys think you know what that's going to mean, you're in for another -- you know, think again.

So, it was a -- it was a very odd statement, and the -- it's in my -- I put it in my -- I think it's quoted in my testimony. It was certainly in my expert report, and we could -- we can read it, but I don't know whether anyone really understood what was meant by that.

Q. Okay, you don't disagree that the FDA, in fact, did acquiesce in the Mova decision.

A. Oh, no, they absolutely -- absolutely acquiesced up until they de-acquiesced in November.

Q. Okay. And you don't disagree that an FDA representative in May of 1997 announced that the FDA was going to acquiesce in Mova pending appeal?

A. I -- she stated it in response to a question, yes.

Q. And the announcement by this FDA official of FDA's intention to acquiesce in Mova was reported in the May 26th, 1997 Pink Sheet. Isn't that correct?

A. Yes.

Q. And The Pink Sheet is a pharmaceutical industry news publication, isn't it?

A. Trade press, yes.

Q. And you consider The Pink Sheet generally to be accurate and reliable, don't you?

A. Yes, as far as trade press go, it's a good one.

Q. And you agree that The Pink Sheet is an important trade press for the pharmaceutical industry, don't you?

A. Yes, I do.

Q. Now, at the top of page 4 of your direct testimony in paragraph 8, you state that, "At this meeting," referring to the May 21st, 1997 public meeting, "a single FDA attorney indicated that for the time being, the Agency," and referring to the FDA, "would abide by Mova in future exclusivity

determinations while continuing to disagree with the decision," correct?

A. Yes.

Q. And also at page 4 of your direct testimony in paragraph 9, again referring to the May 21st, 1997 announcement of FDA's acquiescence in Mova, you characterized the person who made the announcement for FDA as "a low-level FDA official." That's in line 11. Is that correct?

A. Yes.

Q. Now, you know who the single FDA attorney and low-level FDA official was that announced the FDA's acquiescence in Mova, don't you?

A. Yes, I know her very well.

Q. It was Elizabeth Dickinson, wasn't it?

A. Yes.

Q. And at the time of announced acquiescence in Mova, Ms. Dickinson was FDA's Associate General Counsel for Drugs?

A. No, her title was I think Associate Chief Counsel, and she was one of six or seven Associate Chief Counsels at FDA.

Q. The Pink Sheet article refers to her as Associate General Counsel, I believe. Is that correct?

A. I don't -- I don't know. I don't have it here

in front of me, but I mean that -- her title was Associate Chief Counsel.

Q. Now, at the time, Ms. Dickinson was the attorney in the FDA's General Counsel's Office responsible for dealing with Hatch-Waxman Act 180-day exclusivity issues on behalf of the agency, wasn't she?

A. She certainly was one of the -- one of them, yes.

Q. Now, you're certainly not claiming that Ms. Dickinson never made the announcement of FDA's acquiescence in Mova.

A. No.

Q. And you're not claiming, are you, that Ms. Dickinson was not authorized to make the announcement of the FDA's acquiescence in the Mova District Court decision, are you?

A. Well, I don't know whether she was authorized or not. She made the statement at this hearing -- I'm sorry, at this meeting. I subsequently talked with her about it at a later date and asked her, and she was kind of surprised that -- that was the first time it had ever been talked about. I have no idea whether she was authorized or not, but she made the statement.

Q. She wasn't fired subsequently, was she?

A. No, no.

Q. Now, even if the FDA hadn't acquiesced in the Mova District Court decision, any first Paragraph IV ANDA filer that was denied 180-day exclusivity by the FDA based on not having met the successful defense requirement could have sued in Federal Court in the District of Columbia, couldn't it?

A. Yes.

Q. And based on the reasoning of the District Court in both Mova and the Inwood decisions, there is some reason to believe that if a first ANDA filer who was denied exclusivity for not having met the successful defense requirement had sued, they would likely win in District Court in the District of Columbia. Isn't that correct?

A. I think that's a fair assumption. That was certainly FDA's assumption.

Q. Okay. Now, page 7 of your direct testimony, the last sentence of paragraph 12, you state that, "The Mova case did not involve the settlement of litigation, and the Court of Appeals did not express -- address exclusivity in the context of a settlement," correct?

A. I'm sorry, what --

Q. Page 7, paragraph 12.

A. Yes.

Q. Okay. Now, nothing in the Hatch-Waxman Act,

the statute itself, says that a first Paragraph IV ANDA filer must refrain from settling patent litigation in which it's involved in order to be entitled to 180-day exclusivity, does it?

A. No.

Q. And nothing in the Hatch-Waxman Act itself says that in order to be eligible for 180-day exclusivity, the first Paragraph IV ANDA filer that settles in a patent infringement litigation must do so with a finding that the patent at issue was unlawful and not infringed, does it?

A. No, there is nothing in the statute that says that.

Q. Okay. And the reasoning of the District Court and the Court of Appeals in Mova was that the requirements for eligibility for 180-day exclusivity were clear on the face of the statute, correct?

A. Yes.

Q. And that the FDA had no authority to add an additional requirement, in that case the successful defense requirement. Is that correct?

A. It had -- the court said that the agency's regulation, which enunciated the successful defense requirement, was overly broad. It's what they called its win-first solution, and the court indicated that it

was possible that a more narrowly drawn regulation, which might, in effect, require the -- you know, not have exclusivity for someone who lost might be -- might be all right. So -- but there is no question the court said that there was no -- nothing in the statute that addressed either the requirement that the litigant be successful or -- it didn't say anything about settlement.

Q. And the court said that adding the successful defense requirement in the face of a statute which was clear as to what was required for exclusivity was improper. Isn't that correct?

A. Adding the successful defense requirement as expressed in FDA's regulation was improper, yes.

Q. Now, I want to move on to the court decision trigger question which you were asked. I believe in your oral testimony you said that you agreed with Mr. Hoffman's conclusion about the state of the court decision trigger on June 17th, 1997, the date of the Schering-Upsher settlement agreement. Is that correct?

A. No, no, I -- I don't think so. I think he lumped -- what I said was on June 17th, the court -- the trigger situation where a court other than the court in which the first filer was litigating its case could trigger its exclusivity was a -- I mean, I

suppose it's a possibility, but it was kind of remote, because it hadn't come up before. I mean, there was a citizen petition on file with FDA. There was no decision, no one outside of FDA knew what they would do.

So, I don't think -- to the extent Mr. Hoffman said that the trigger was -- there was a substantial possibility of that second court decision being a trigger on June 17th, I would disagree with him. On the -- in January of '98, there I said we just have a difference in degree.

Q. Okay, I believe Mr. Hoffman said that there was no substantial reason to believe on June -- prior to June 17th --

A. Okay, if that's what he said, then I -- then I agree.

Q. Then you agree with him?

A. Yeah.

Q. Okay. That specific point was not addressed in your written direct testimony.

Okay, now, you do agree that -- okay, and you state in your testimony, I believe, that, "While I agree that as of January 23rd, 1998, there was a possibility that a decision in the Schering-ESI litigation could trigger the running of any 180-day

exclusivity period to which Upsher was entitled, in light of the status of the Granutec case, I would not characterize this possibility as substantial."

A. That's correct.

Q. Is that correct?

So, if I understand you correctly, you disagree with -- your disagreement with Mr. Hoffman on this point is solely one of degree?

A. Yes.

Q. Okay. You believe that on January 23rd, 1998, there was a possibility that a decision in the Schering-ESI litigation could trigger any 180-day exclusivity to which Upsher was entitled?

A. Yes.

Q. And Mr. Hoffman believes that on the date January 23rd, 1998, there was a substantial possibility of a decision in the Schering-ESI litigation triggering any 180-day exclusivity to which Upsher was entitled. Is that correct?

A. I think that's what he said, yes.

Q. Okay. Now, at the time you initially stated in your expert report your disagreement with Mr. Hoffman on the degree of possibility of the trigger of the Schering-ESI -- settlement of the Schering-ESI case triggering Upsher's exclusivity, you didn't know what

Mr. Hoffman meant when he used the term "substantial," did you?

A. That's right.

Q. And do you recall in your deposition you stated that you took Mr. Hoffman's use of the word "substantial" to mean, "considerably more likely than not, so that, you know, certainly let's say greater than a 50/50 likelihood"?

A. I don't recall that specifically, but I think that's what I said.

Q. Okay. And I asked you at your deposition, "Do you recall, if not substantial, how you would characterize the possibility of a decision in the Schering-ESI litigation triggering any 180-day exclusivity," and you said that by possible, you meant a reasonable probability, somewhere -- "In my view, it's somewhere in the neighborhood of 50/50."

Do you recall that?

A. Yeah, I recall saying that.

Q. Okay. So, in your opinion, there was something like a 50/50 chance of the Schering-ESI settlement agreement triggering any exclusivity to which Upsher was entitled as of January 23rd, 1998.

A. Yeah, I guess I would recharacterize that now as saying no more than 50/50, that that's sort of -- I

think that's -- that's essentially what I was saying. I mean, as you know, when lawyers give estimates, they're pretty imprecise. My -- my feeling is that up to a 50/50 possibility, yes.

Q. Okay. So, now you're saying up to a 50/50.

A. Yes.

Q. Do you recall saying somewhere in the neighborhood of 50/50 at your deposition, though?

A. Yes. Yes, I do.

Q. Okay. And do you still agree that it's somewhere in the neighborhood of 50/50?

A. It's certainly no more than 50/50. I -- you know, when you say -- when I said in the neighborhood, that could be anywhere from -- really, as I said, I think there was a possibility, because FDA had -- had made that -- that finding, so to try and put numbers on it, you know, I would say 30 to 50, which is in the neighborhood of 50/50.

Q. You believe 30 percent is in the neighborhood of 50/50?

A. Yeah, when you're talking about litigation, likelihood of litigation, of an outcome, you're -- I mean, it's a guess. That's -- that's what it is. It's a best guess based on what you know.

Q. Would you please take a look at what was marked

CX 1546 in your binder, which is your deposition testimony?

A. Um-hum.

Q. And in your deposition, I asked:

"QUESTION: Okay, I'm just -- I'd like to know what you understand -- excuse me.

'if not substantial, how would you characterize the likelihood that --

"ANSWER: I just said that it was possible, which means to me there's a -- you know, a reasonable probability, somewhere in -- in my view, it's somewhere in the neighborhood of 50/50."

Is that correct?

A. Yes.

Q. And you're now saying that 30 percent is somewhere in the neighborhood of 50/50?

A. Yeah, in the range of what we were talking about. In my view, if it was a remote possibility, it would be around -- down around, you know, 10 percent, a reasonable possibility is somewhere between 30 and 50, a likelihood is more than 50, a substantial possibility, I wasn't sure what Joel meant at that time. I think after looking at his testimony in this case, I'm still not sure what he meant, somewhere between 20 and 80 it looked like to me, but my view --

I mean, looking at what I said there and what I feel now, I don't think it's all that different. I think it's certainly no more than a 50/50 chance.

Q. Okay, now I'd like to address the conclusion of Mr. Hoffman with which you disagree, and that is Mr. Hoffman's conclusion that since June 1st -- since no later than June 1st, 1998 and through February the 28th, 2002, Upsher-Smith has been entitled to 180-day exclusivity that bars approval of ESI's or any other submitter's Paragraph IV ANDA for 20 milliequivalent potassium chloride extended release tablets, okay, and you disagree with Mr. Hoffman's conclusion to that effect. Is that correct?

A. Yes, what I said was that the -- I think I believe I said that the exclusivity was far from certain. That's what I believe I said.

Q. Now, as I understand your argument, you believe that someone could have challenged Upsher's exclusivity.

A. Yes.

Q. Based on Upsher having settled its patent infringement litigation with Schering and based on its not having come to market with its own approved generic product. Is that correct?

A. No, I said based on the fact that it settled

the litigation, took a license, was not on the market at the -- at the time someone would look at this, and therefore -- and was no longer contesting either the validity or noninfringement of the statute.

Q. And you're arguing that the reason you believe Upsher's exclusivity was subject to challenge was based on the reasoning of the FDA in responding to the Teva petition. Is that correct?

A. That's right.

Q. Okay. And in the Teva petition, the FDA argued that the situation addressed in the Teva petition was that Mylan was the first Paragraph IV ANDA filer, and it had settled its litigation with Pfizer and hadn't brought its approved generic product to market for more than a year after final FDA approval of the drug.

A. Right.

Q. Is that correct?

A. That's correct.

Q. Okay. And the FDA's position in response to the Teva petition was that a settlement between a pioneer and a first Paragraph IV ANDA filer under which the filer is no longer participating in litigation and intending to prove that the product doesn't infringe the listed patent and where the first filer is not marketing its own FDA approved ANDA product effectively

changes the filer's certification from a Paragraph IV to a Paragraph III certification. Is that correct?

A. That was the FDA's reasoning, yes.

Q. Right, and that effective change to a Paragraph III eliminates the entitlement of the filer to 180-day exclusivity. Is that correct?

A. That was FDA's argument, yes.

Q. Right. Now, in fact, nobody did challenge Upsher's entitlement to exclusivity, did they?

A. No.

Q. And the FDA's stated position regarding Upsher's entitlement to 180-day exclusivity is and has been that Upsher is the first ANDA filer with a Paragraph IV certification for generic 20 milliequivalent potassium chloride extended release tablets, is or at least was until February 28th entitled to 180-day exclusivity under the Hatch-Waxman Act. Isn't that correct?

A. Yes, FDA granted exclusivity in either the approval letter or a subsequent letter, and there was never any reason to examine it, so they -- they had exclusivity until the expiration on the 28th.

Q. The FDA gave Upsher final approval for that product, didn't it?

A. Yes.

Q. Okay. And the FDA sent a letter in January of 1999 to Upsher specifically telling it that it was entitled to 180-day exclusivity. Isn't that correct?

A. Yes.

Q. And the FDA's January 28th, 1999 letter to Upsher told Upsher that as the first ANDA filer with a Paragraph IV certification for the generic potassium chloride extended release tablets, Upsher was entitled to 180-day exclusivity for that product. Isn't that correct?

A. Yes, I think that was probably the same language they used in giving it to Mylan.

Q. Now, both the November 19 -- November 20th, 1998 letter from FDA to Upsher, which it told it that it had received final approval, and the January 28th, 1999 follow-up letter from FDA to Upsher telling it that it was entitled to 180-day exclusivity, both those letters specifically state that Upsher's patent infringement litigation with Key Pharmaceuticals had been terminated by a court-issued stipulation and order of dismissal. Isn't that correct?

A. I believe so, yes.

Q. Would you take a look at CX 59 and CX 611.

A. I'm sorry, CX --

Q. CX 59 and CX 611.

A. I don't think there is a 59. Do you mean 595?
Q. No, no, this would be toward the back.
A. Oh, I'm sorry. And the other one, 611?
Q. Yes, they are right in order.
A. Okay.
Q. Okay, do you see the second highlighted part?
A. Yes.
Q. So, the FDA knew that the litigation between Upsher and Schering had been dismissed and Upsher and Schering were no longer pursuing that litigation. Isn't that correct?
A. Yes, otherwise they couldn't have issued the approval letter.
Q. And CX 611 says the same thing at the bottom. Isn't that correct?
A. Yes.
Q. So, the FDA was aware as early as November 20th, 1998, certainly, wasn't it, that Upsher wasn't pursuing the patent infringement case with Schering to a determination on the merits -- Schering wasn't pursuing it against Upsher in that case?
A. No, it was simply aware that the case was settled, and they obviously were not aware of the terms of the settlement, because they go on in that same exhibit --

Q. Excuse me, I asked you whether the FDA was aware that the litigation wasn't being pursued at that time.

A. They were -- they were aware that the litigation had been settled, yes.

Q. Right. And that settlement means that the litigation wasn't being pursued, correct?

A. They might have won. Upsher might have won the case. They didn't know whether they won, lost or did what.

Q. Okay.

A. It was just dismissed. It could have been dismissed with a finding of noninfringement.

Q. It doesn't say that in either of the letters, does it?

A. No, it doesn't say anything. It just says all they know is what Upsher told them, which is the case has been settled.

Q. Okay. Now, you point out in your direct testimony on page 10, paragraph 18, lines 14 through 16 that the January 28, 1999 letter from FDA to Upsher stated that FDA "expects that you," referring to Upsher, "will begin commercial marketing of this drug," and referring to the 20 milliequivalent potassium chloride extended release tablets, "in a prompt

manner," doesn't it?

A. Yes.

Q. Okay. And Upsher didn't start commercial marketing of its generic K-Dur 20 product until September 1st, 2001. Isn't that right?

A. That's correct.

Q. And September 2001 was more than four years after Upsher settled with Schering in June of 1997. Is that correct?

A. If that's -- if that's when they settled. I don't -- I don't know exactly when they -- when they settled. The second letter is dated '99 when they wrote that, so...

Q. Well, you know Schering and Upsher entered into a settlement agreement in June of 1997.

A. I'm sorry, yes, June of '97, that's right.

Q. And September 1st, 2001 was two years and almost ten months after Upsher received final FDA approval for its generic K-Dur 20 product in November of 1998. Isn't that correct?

A. Say that again, I'm sorry.

Q. September 1st, 2001 --

A. Oh, yes, yes, right.

Q. Okay. And September 1st, 2001 was two years and about seven months after FDA told Upsher in its

January 28, 1999 letter that it expected Upsher to begin commercial marketing in a prompt manner, isn't it?

A. Yes.

Q. Okay. Now, in your opinion, do you believe that Upsher's commencement of marketing of its generic K-Dur 20 on September 1st, 2001 constituted Upsher doing so in a prompt manner?

A. I don't know the answer to that. I guess the way I would answer that is if I were another generic applicant with my approval held up, I would certainly argue that that was not a prompt manner.

Q. Now, in its response to the Teva petition, FDA stated that Mylan's failure to commercially market its approved product for more than a year was sufficient delay to in part justify FDA's considering that Mylan had effectively changed its certification from a Paragraph IV to a Paragraph III. Isn't that correct?

A. Yes.

Q. Now, the FDA didn't change its position as stated in its January 28, 1999 letter to Upsher that Upsher was entitled to 180-day exclusivity, did it?

A. They had no reason to. No one asked it to.

Q. The FDA didn't take any action to revoke or rescind that January 28, 1999 letter to Upsher, did it?

A. No.

Q. Okay. So, you've never seen anything to indicate that the FDA modified or revoked its position relative to Upsher's exclusivity that was contained in the January 1999 letter to Upsher.

A. No, that's not --

Q. Correct?

A. -- that's not what I testified to. I simply believe that had someone requested it that FDA I think would have done so.

Q. But the FDA didn't --

A. No, FDA did not, that's correct.

Q. And Upsher didn't change its Paragraph IV certification to a Paragraph III certification, did it?

A. No, it did not.

Q. And the FDA didn't make any effort to change Upsher's certification, did it?

A. No.

Q. So, you have no doubt that in terms of FDA's stated official position as to Upsher's entitlement to exclusivity, that it is -- it has continuously taken the position that Upsher has that exclusivity. Is that correct?

A. No, I wouldn't characterize it that way. I would say that FDA on this January 28, '99 letter,

where they, in effect, granted the exclusivity, FDA had no occasion to look at it ever again.

Q. FDA never changed that -- that statement as to -- as to Upsher's exclusivity?

A. FDA didn't do anything.

Q. FDA has -- has the FDA in your opinion continued to acknowledge that Upsher has had exclusivity?

A. I don't know unless they sent a letter after this one. I don't know that.

Q. Have you looked at the Orange Book concerning Upsher's entitlement to exclusivity on its K-Dur 20 product?

A. Have I looked at the Orange Book? I don't recall. I don't recall if it's listed in there. I mean, if you show me it, I can look at it.

Q. I was just going to do that. Would you please take a look at CX 1653, please.

A. Yes. Is that the last --

Q. It's the last exhibit in the binder.

A. Go ahead.

Q. Do you know what CX 1653 is?

A. It looks like the web site.

Q. The FDA's web site?

A. Yes.

Q. The electronic web site. Is that correct?
A. Correct.
Q. And are you aware that there is an electronic Orange Book section available on the FDA's web site?
A. Yes.
Q. Okay. Please turn to page FTC 0022686.
A. I'm sorry, I'm not -- oh, I --
Q. It's toward the back.
A. I'm sorry, I'll look at this one up here.
Q. It's about three-quarters of the way back, at the lower right there's small numbers preceded by FTC.
A. At the lower right? Okay, I'm sorry. Yes, what is it?
Q. Third page from the end, FTC 00022686.
A. Okay, I have it. I have it.
Q. Okay. What does this tell you about the FDA approval status of Upsher-Smith's Klor Con 20 -- M20 product?
A. It was approved on November 20, 1998.
Q. Okay. Now, please turn to the next page. What does this page tell you about Upsher-Smith's 180-day exclusivity status for Klor Con M20?
A. That it has exclusivity up until February 28, 2002.
Q. And in this instance, can you identify the date

of this electronic web site? It's in the far -- lower right-hand corner of each page.

A. Oh, it's -- okay, that looks like January 28th, 2002.

Q. So, certainly as of January 28th, 2002 --

A. Oh, there's -- right, there is no question Upsher, in fact, had exclusivity up until February 28th. There is no question about that.

Q. Now, you've stated that you believe that somebody may be in a position to challenge Upsher's exclusivity. Is that correct?

A. Yes, if there were a -- someone with standing could -- could have challenged it, another ANDA applicant that either was blocked or thought it might be blocked.

Q. Could the FDA -- could the FDA itself have decided to give final approval or to initiate to giving final approval to any tentatively approved ANDA holder despite Upsher's exclusivity without that other ANDA filer requesting FDA to do so?

A. I don't think so. I mean, it's -- as a practical matter, it would never happen. Whether they could, I really don't know.

Q. Would ESI Lederle have been in a position to challenge Upsher's exclusivity?

A. If ESI Lederle were blocked, they -- yes, they would have had standing to do so.

Q. ESI Lederle has tentative approvals for --

A. Yes, they would have standing to do so.

Q. And ESI Lederle has received tentative approval from the FDA for its 20 milliequivalent potassium chloride extended release tablets, hasn't it?

A. That's my understanding, yes.

Q. You state that at page 10 of your direct testimony.

A. Okay.

Q. Don't you? Paragraph 18, five lines from the bottom.

A. Yes, it does have approval.

Q. Okay. It received approval, tentative approval, from the FDA by letter dated May 11th, 1999. Is that correct?

A. Correct.

Q. And that May 11th, 1999 tentative approval letter to ESI from the FDA told ESI that it would be eligible for final approval after the conclusion of the first Paragraph IV certifying ANDA filer's 180-day exclusivity period, right?

A. That's right.

Q. Okay. And they told ESI Lederle that they

would have to wait until that 180-day exclusivity period was triggered and had passed by the first Paragraph IV certifying ANDA filer. Isn't that correct?

A. Yes.

Q. Okay. And the first Paragraph IV ANDA filer whose 180-day exclusivity was blocking final approval of ESI Lederle's ANDA was Upsher. Isn't that correct?

A. Yes.

Q. Okay. Now, as far as you know, ESI Lederle still has tentative approval as stated in the May 11th, 1999 FDA letter to ESI. Is that correct?

A. As far as I know, yes.

Q. ESI hasn't received final approval, has it?

A. I haven't looked. I don't know.

Q. That would show up in the --

A. It would show up in the --

Q. -- in the electronic Orange Book, also?

A. Yes.

Q. Would you take a look again at CX 1653, and turn to page FTC 0022679.

A. Um-hum. Yes, that would appear to indicate that they are -- as of January 28th, they're still tentatively approved, which would be consistent with the fact that the exclusivity for Upsher didn't expire

until February 28th.

Q. Okay. So, final approval of ESI Lederle's ANDA is blocked -- was blocked until February 28th, 2002 by Upsher's 180-day exclusivity. Is that correct?

A. Yes, yes.

Q. And presumably any other tentatively approved ANDA holder for that same product was also blocked from final FDA approval until February 28th, 2002, when Upsher's exclusivity expired. Isn't that correct?

A. Yes.

Q. So, ESI Lederle was in a position, then, you believe to challenge Upsher's exclusivity, correct?

A. They were potentially in a position to do that, yes.

Q. They are blocked --

A. They would have had standing, yes.

Q. They would have had standing. They were blocked by Upsher's exclusivity, and they had tentative approval for the same product, correct?

A. That's both -- both of those things are true, but they may also have been blocked, for example, by a 30-month stay, which conceivably could have expired after the exclusivity expired. I mean, there are a number of factors that would weigh into whether someone would want to challenge it. You would want to have --

the only thing blocking you, you would want to -- in order to take on the expense of challenging FDA, would be the exclusivity.

In other words, Mylan in the Mylan case was free to go to market but for the -- the 180-day blockage. If Mylan, let's say, were subject to a 30-month stay on litigation, I'm not sure they would have had, you know, a case in controversy.

Q. Well, ESI and Schering settled their patent infringement litigation in 1998, didn't they?

A. That's my understanding, yes.

Q. So, any 30-month stay presumably would have long since expired.

A. That's right.

Q. Okay. And Schering and ESI settled their patent infringement litigation in -- I guess it was January of 1998. Isn't that correct?

A. I believe so.

Q. And as part of that settlement agreement, ESI agreed not to enter the market with any generic 20 milliequivalent potassium chloride extended release tablets before January 2004. Is that correct?

A. I believe that's correct.

Q. Okay. And part of Upsher's settlement of the patent infringement litigation with Schering was that

Upsher wouldn't enter the market with its generic product until September of 2001. Isn't that correct?

A. That's correct.

Q. Okay. And 180 days after September 2001, September 1st, was February 28th, 2002, right?

A. Right.

Q. Okay. So, even if ESI challenged Upsher's exclusivity at the FDA and won at the FDA and on any court appeals, ESI still couldn't have entered the market before Upsher's exclusivity expired, unless ESI was willing to breach its settlement agreement with Schering. Isn't that correct?

A. Yeah, presumably so, yes.

Q. Now, returning to your argument about the possibility of someone challenging Upsher's exclusivity based on the FDA's response to the Teva petition, in its response to the Teva petition in February 2001, the FDA changed the Paragraph IV certification by Mylan in that case to a Paragraph III based on Mylan's settlement of its patent infringement litigation and its failure to bring its own product to market. Is that correct?

A. Yes.

Q. Okay. And FDA asserted that as a result of this change to a Paragraph III certification which it

had implied, Mylan was no longer entitled to 180-day exclusivity, correct?

A. Yes.

Q. And that action by the FDA in determining that Mylan had implied a change from a Paragraph IV to Paragraph III certification was challenged in Federal Court, wasn't it?

A. Yes, I testified, yes.

Q. And that was in the Northern District of West Virginia in the case of Mylan vs. Thompson. Is that correct?

A. That's correct.

Q. Now, in Mylan vs. Thompson, the District Court rejected and overruled the FDA's attempt in its response to the Teva petition to change a Paragraph IV certification by Mylan to a Paragraph III certification, didn't it?

A. That's correct.

Q. Okay. And the District Court in Mylan vs. Thompson said that the FDA's interpretation was unreasonable, didn't it?

A. I believe it did, yes.

Q. Um-hum. And the District Court said that there was no statutory provision which grants to FDA either expressly or implicitly the authority to change a

Paragraph IV certification to a Paragraph III certification. Isn't that correct?

A. That's what the District Court said, yes.

Q. And the District Court also noted as a second reason that the FDA's action was unreasonable was that there was no FDA regulation that provided any basis for such a change, didn't it?

A. I don't recall specifically, but I think there was something like that in there.

Q. Take a look at CX 695, please. I'm sorry, I believe it's CX 1695.

A. How far back --

Q. It's about in the middle.

A. Just a minute. Okay. What page were you citing?

Q. Page 22.

A. Twenty-two?

Q. And the Court there says, "There is no FDA regulation that provides any basis for such a change." That's the second reason.

A. Right.

Q. And the first reason is that there's no statutory provision which grants to the FDA, either expressly or implicitly, the authority to change a IV certification to a III certification. Is that correct?

A. That's correct.

Q. And then third, the District Court also stated that a third reason that the FDA's position was unreasonable was that its ruling was based on "a presumption that is inadequately reached in this particular case," didn't it?

A. Yes.

Q. And that presumption by the FDA was that because Mylan settled its patent infringement litigation and hadn't marketed its approved ANDA product, the FDA presumed that Mylan believed that its product might infringe the patent, and therefore it was waiting until the patent expired. Is that correct?

A. I believe that's the case. I'm not sure. They don't seem -- they don't specify it here, but I think that was the presumption.

Q. Okay. Take a look, would you, please, at CX 613, page 6. It's halfway back.

A. Halfway back?

Q. I believe it's right before the exhibit we just pulled out, 1695.

A. Okay, I've got it.

Q. Do you see CX 613?

A. Yes, I do.

Q. What is that?

A. It's the response to the citizen's petition filed by Teva in the -- challenging Mylan's 180-day exclusivity.

Q. This was the FDA's response to it?

A. This is the FDA's response.

Q. And in the middle highlighted portion, about halfway through, beginning with the sentence, "These facts lead."

A. Um-hum.

Q. Does that clarify for you what the court meant by FDA's presumption?

A. Yes, I think it does.

Q. That says, "These facts lead FDA to presume that Mylan believes the product described in its ANDA may infringe the listed patent and is therefore waiting until patent expiry before marketing its own product," correct?

A. That's right.

Q. And the fourth reason that the District Court found the FDA's interpretation to be unreasonable was the FDA's reliance on the case of Mylan vs. Henney. Is that correct?

A. That's right.

Q. And the District Court in Mylan vs. Thompson found Mylan vs. Henney to be distinguishable and

inapplicable because in Mylan vs. Henney, the ANDA filer, by its own actions, expressly changed its certification from a Paragraph IV to a Paragraph III. Isn't that correct?

A. That's correct.

Q. And that was not the case with regard to the issue raised in the Teva petition. Isn't that correct?

A. That's right.

Q. So, the District Court in Mylan vs. Thompson apparently disagreed rather strongly with the position that the FDA took in response to the Teva position. Isn't that fair to say?

A. That's fair to say.

Q. There were at least four reasons that the District Court found the FDA's actions to be unreasonable. Is that correct?

A. Yes.

Q. Now, the FDA appealed the adverse District Court decision in Mylan vs. Thompson to the Fourth Circuit Court of Appeals, didn't it?

A. Yes, it did.

Q. And the FDA pressed its argument as to the rightness of its position in that appeal. Is that correct?

A. Yes.

Q. That appeal was dismissed, wasn't it?
A. It was dismissed by Mylan.
Q. The opinion wasn't --
A. There was never an opinion.
Q. The District Court's opinion was not overturned.
A. At -- not that I'm aware of, no. It was -- the appeal was dismissed by Mylan. I'm not aware that FDA has moved to vacate the District Court's opinion.
Q. Would you turn to CX 1696, please. While you're at it, you might as well pull 1697 out, also, which is immediately following 1696.
A. Yes, I have it.
Q. Okay. Do you recognize what 1696 is? And it actually is a couple of documents put together.
A. I think it's this -- well, it looks like it's the docket and then a stipulation -- a motion for voluntary dismissal filed by Mylan.
Q. And the last page?
A. Is the order dismissing the action.
Q. Okay. And on the bottom of page 596, of the docket sheet, the first part of that exhibit, 1696?
A. Order filed granting motion to dismiss.
Q. Right. This doesn't indicate that there was any order of vacation --

A. No, that's what I said.
Q. And if you take a look at 1697.
A. Yes, okay.
Q. And do you recognize what this is, what CX 1697 is?
A. It looks like the civil docket at that court in West Virginia.
Q. Okay. And the last two pages of that exhibit?
A. Is a stipulation and order.
Q. And that order is dismissing the case, correct?
A. Yes, I'm -- I'm not a litigator, so I'm not sure what it means to be dismissed without prejudice, but it's dismissed.
Q. So, there's no indication certainly in these documents that the District Court decision in Mylan vs. Thompson was vacated.
A. No, oh, absolutely not.
MR. NARROW: Your Honor, at this time I would like to move the admission of CX 1696 and CX 1697.
MR. LOUGHLIN: No objection, Your Honor.
MR. CURRAN: No objection, Your Honor.
JUDGE CHAPPELL: CX 1696 and CX 1697 are admitted.
(Commission Exhibit Numbers 1696-1697 were admitted into evidence.)

MR. NARROW: Thank you, Your Honor.

JUDGE CHAPPELL: Mr. Narrow, how much more cross do you have?

MR. NARROW: Perhaps five minutes.

JUDGE CHAPPELL: Proceed.

MR. NARROW: Thank you.

BY MR. NARROW:

Q. So, the District Court action then was dismissed in December of last year in Mylan vs. Thompson. Is that correct?

A. Yes.

Q. So, in the one court challenge to the FDA's attempt to impliedly change a first Paragraph IV ANDA filer's certification from a Paragraph IV to a Paragraph III based on the filer's having settled its patent litigation and not coming to market with its own product, the FDA was overruled. Is that correct?

A. That's correct.

Q. Okay. And the FDA's attempt to apply such a certification change from a Paragraph IV to a Paragraph III was found by the District Court that heard the case to be unreasonable. Isn't that correct?

A. It was overturned by the District Court.

Q. The District Court found the FDA's actions unreasonable, used those words, didn't it?

A. Yes, I believe they did.

Q. Okay. You've already agreed that the District Court's decision wasn't reversed on appeal or vacated. Is that correct?

A. That's right.

Q. And no other court has reached a decision contrary to that of the District Court in Mylan vs. Thompson, has it?

A. It's never come up before.

Q. No court has reached a different determination, has it, on that issue?

A. Not that I'm aware of.

Q. And no other court has rejected the analysis and reasoning used by the District Court in Mylan vs. Thompson in holding that the FDA's position in responding to the Teva petition was unreasonable, has it?

A. No.

Q. So, any challenge to Upsher's 180-day exclusivity would have required the FDA to continue to apply the position it adopted in response to the Teva petition --

A. No, I disagree with that.

Q. You disagree with that?

A. Yes, because the challenge could have come in

1999, it could have come in 2000, and that challenge could have been the focus of the case. In other words, clearly today you have this decision, but you also have Upsher's exclusivity expiring, so it's irrelevant, but had someone challenged the Upsher exclusivity at the same time Teva wrote its petition, my feeling is FDA probably would have come out the same way. You probably would have ended up in court, may have ended up in a different court.

I don't know how it would have come out, but what I was asked to respond to in my testimony or in my -- initially my statement, then in my testimony, was Mr. Hoffman's assertion that throughout that entire period, they were entitled to exclusivity. So, a lot of this is timing. This case wasn't decided until sometime in 2000, in 2001. FDA continued to take the position in the brief.

So, I think if someone wanted to challenge that, it could have been challenged in '99, it could have been challenged in 2000, and the same reasoning would have applied. You would have had a petition like you had in Teva, and you probably would have gotten the same answer.

Q. And the same reasoning that the court adopted in Mylan vs. Thompson, finding four reasons why the

FDA's position was unreasonable, could well have been adopted by the court in any challenge. Isn't that correct?

A. Yes, there is no question FDA could have lost.

Q. Okay, and there is no precedent that would indicate that FDA would be likely to win, is there, based on the position it took in the Teva case?

A. No, only one case at the moment.

Q. Okay, thank you. And nobody actually did challenge --

A. No, absolutely not, no one challenged.

Q. Upsher's exclusivity began running September 1st, 2001 and continued through February 28th, 2002. Isn't that correct?

A. That's correct.

MR. NARROW: No further questions, Your Honor.

MR. LOUGHLIN: I have some redirect, Your Honor.

JUDGE CHAPPELL: Go ahead.

REDIRECT EXAMINATION

BY MR. LOUGHLIN:

Q. Mr. Safir, when FDA revoked Mylan's exclusivity in response to a citizen petition by Teva Pharmaceuticals, they did that only in response to a citizen petition. Isn't that correct?

A. That's correct.

Q. Are you aware of FDA revoking exclusivity of any ANDA filer on its own initiative?

A. No, I'm not.

Q. Now, you mentioned that no ANDA filer challenged -- did, in fact, challenge Upsher's eligibility for 180-day exclusivity. Do you recall that?

A. Yes, I do.

Q. Do you know whether any ANDA filer had an incentive to challenge Upsher's eligibility?

A. I do not, no.

Q. Mr. Narrow asked you some questions about ESI. Do you recall that?

A. Yes.

Q. And he asked you if you were aware that ESI got tentative approval in May of 1999. Do you recall that?

A. Yes.

Q. And he also asked you if you knew that ESI had settled with Schering in 1998. Do you recall that?

A. Yes.

Q. And he asked if you were aware that in 1998, under the terms of that settlement, ESI had agreed that it would market only under a license from Schering in January of 2004. Do you recall that?

A. Yes.

MR. LOUGHLIN: I have no further questions.

JUDGE CHAPPELL: Anything else?

MR. NARROW: No, Your Honor.

MR. CURRAN: Nothing for Upsher, Your Honor.

JUDGE CHAPPELL: What about your SPX 1277, can we resolve that?

MR. CURRAN: Yes, Your Honor.

MR. LOUGHLIN: I was just going to raise that, Your Honor.

MR. CURRAN: Upsher-Smith has no objection to the admissibility of that written testimony.

JUDGE CHAPPELL: Do you still wish to offer it?

MR. LOUGHLIN: Yes, Your Honor, I again move for the admission of SPX 1277.

JUDGE CHAPPELL: SPX 1277 is admitted.

(SPX Exhibit Number 1277 was admitted into evidence.)

JUDGE CHAPPELL: Thank you, sir, you're excused.

What are we looking at tomorrow?

MR. NIELDS: Your Honor, we have two witnesses tomorrow. Unfortunately, I had anticipated that one of them would have gotten on yesterday, but the Kerr testimony lasted much longer than I had anticipated.

I'm afraid my track record that looked good for a while has deteriorated some. I'm hopeful that we can get them both on and off tomorrow, and -- but I think I cannot guarantee that.

JUDGE CHAPPELL: So, are we looking at a full day tomorrow?

MR. NIELDS: Yes, we are looking at a full day tomorrow.

JUDGE CHAPPELL: Did you have something?

MR. CARNEY: Yes, Your Honor, one housekeeping matter, an evidentiary stipulation which I was wondering if the Court would handle it this evening, it would take five minutes, I think, or we can wait until tomorrow, as the Court pleases.

JUDGE CHAPPELL: Tomorrow.

MR. CARNEY: Yes, Your Honor.

JUDGE CHAPPELL: So, we're adjourned until 9:30 in the morning.

(Whereupon, at 6:10 p.m., the hearing was adjourned.)

C E R T I F I C A T I O N O F R E P O R T E R

DOCKET/FILE NUMBER: 9297

CASE TITLE: SCHERING-PLOUGH/UPSHER-SMITH

DATE: MARCH 7, 2002

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the notes taken by me at the hearing on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

DATED: 3/8/02

SUSANNE BERGLING, RMR

C E R T I F I C A T I O N O F P R O O F R E A D E R

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.

DIANE QUADE